Pharmaceutical Manufacturers Association

Facts At A Glance

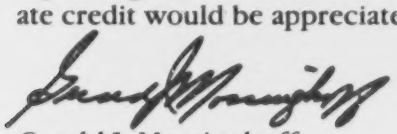
10/88

PMA
STATISTICAL FACT BOOK
August, 1988

Foreword

This publication is a reference guide to the prescription drug industry. It provides some of the key data that describe the operations of the U.S. pharmaceutical industry and the context in which it operates.

We welcome comments on this publication and inquiries for further information. We encourage reprinting of the contents as necessary; appropriate credit would be appreciated.



Gerald J. Mossinghoff
President

August, 1988

The Pharmaceutical Manufacturers Association

The Pharmaceutical Manufacturers Association is a nonprofit scientific, professional and trade organization of more than 100 firms that discover, develop and produce prescription drugs and biological products in the United States. The Association's members produce more than 90 percent of the prescription drugs used in the United States, and about half the free world's supply of prescription drugs. Worldwide pharmaceutical sales of PMA member companies in 1987 totaled an estimated $41.2 billion. PMA members spent $5.4 billion worldwide in 1987 to research and develop new pharmaceutical products.

The mission of the research-based pharmaceutical industry is to satisfy public demand around the world for medicines of the highest quality. To accomplish this mission, firms in this industry discover, develop, manufacture, and market ethical pharmaceuticals, biologicals and diagnostic products. They place special emphasis on innovation and quality, and are committed to supporting comprehensive research and development programs leading to products and services used in the prevention, diagnosis, cure and treatment of disease. As investor-owned private enterprises, pharmaceutical firms seek reasonable returns on their substantial and high-risk investments in research and development.

The Pharmaceutical Manufacturers Association was founded in 1958. It is the successor to the American Association of Pharmaceutical Chemists, organized in 1907 and renamed the American Pharmaceutical Manufacturers' Association in 1922; and to the National Association of Manufacturers of Medicinal Products, founded in 1912 and called the American Drug Manufacturers Association after 1916.

The Pharmaceutical Manufacturers Association is governed by a 36-member Board of Directors that establishes the policies carried out by its staff and sections. The Association has 13 functional units known as sections; these are composed of representatives of member firms who work closely with the Board and staff on numerous projects. The sections are Production, Engineering and Materials Management; Research and Development; Quality Control; Biological; Marketing; Medical; International; Public Affairs, Financial, Law, Personnel; State Government Affairs; and Washington Representatives.

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I. An Overview Of The Pharmaceutical Industry In The U.S.

The research-based pharmaceutical industry is one of America's most important high-technology industries. The creative contributions of the industry add immeasurably to the quality of life of people worldwide.

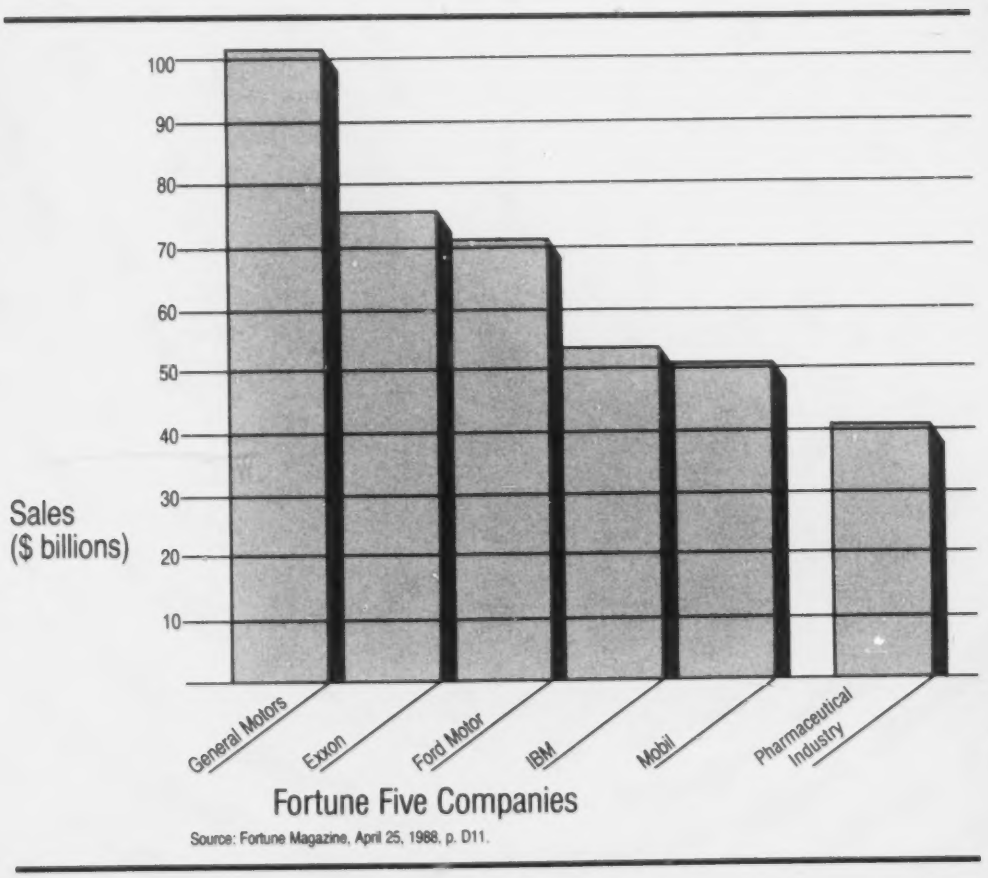
This relatively small, competitive industry also makes major contributions as an industrial entity:

- It is a steady employer of more than 300,000 skilled and productive individuals who are located in facilities throughout this country and the world.
- It leads the world in total sales of pharmaceuticals.
- It pays one of the highest effective federal tax rates of all industries.
- Unlike many other U.S. industries, it has a favorable balance of trade.

A Relatively Small Industry

Compared to other major U.S. industries, the pharmaceutical industry is relatively small. In 1987, total worldwide sales of PMA member firms were $41 billion, making the entire industry smaller than any of the first five companies on the Fortune 500 list.

Sales Of The Fortune Top Five Companies Compared To Sales Of The Pharmaceutical Industry, 1987

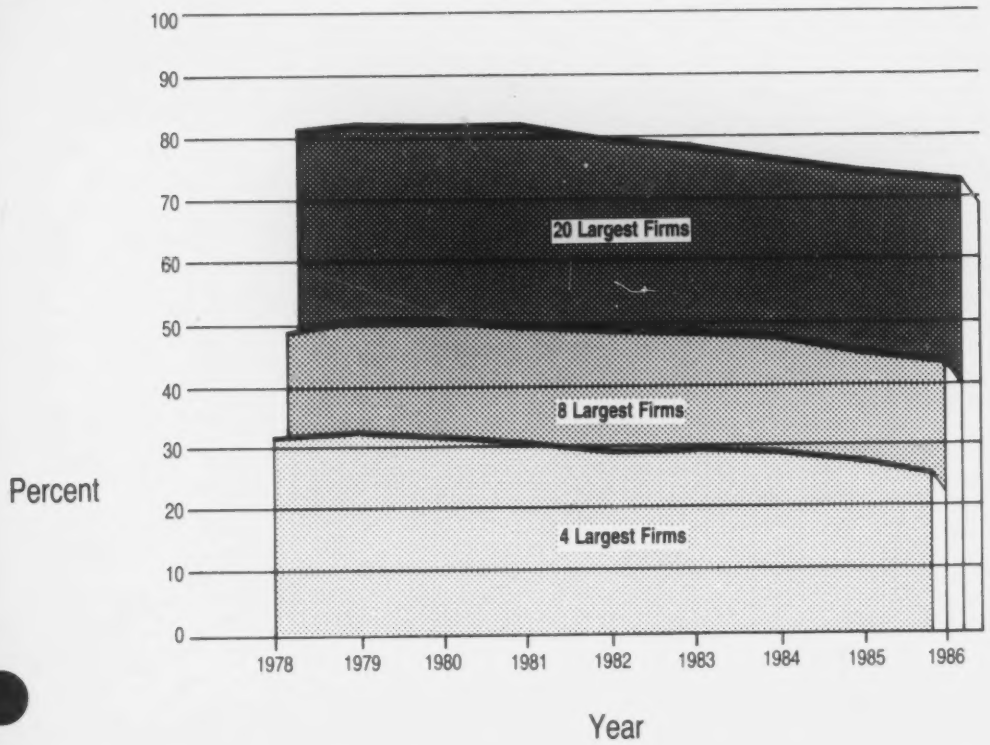


Source: Fortune Magazine, April 25, 1988, p. D11.

The Industry Is Highly Competitive

The pharmaceutical industry is highly competitive. The share of total sales held by the four largest firms accounts for only 25 percent of industry sales; the top eight firms account for less than 50 percent of the market. Not one of the major companies holds more than a 7 percent share of the market.

Concentration Ratios For Firms Measured In Total Prescription Dollars 1978–1986



Source: National Prescription Audit, IMS America, Ltd.

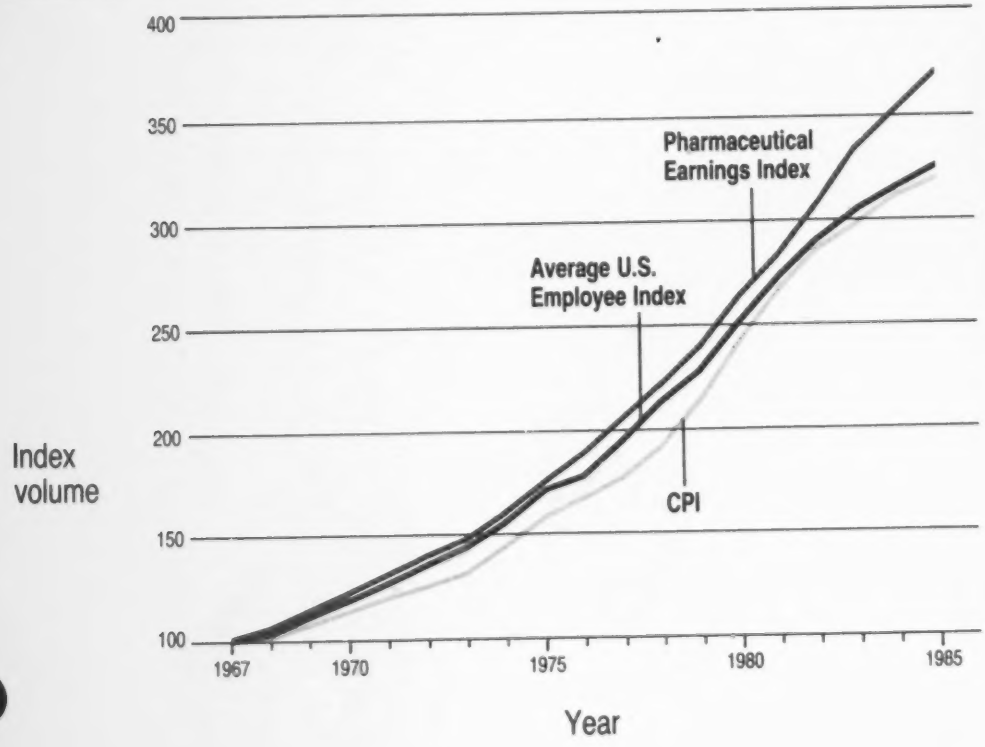
An Industry That Contributes To The Nation's Economy

- As an Employer
- As a Producer
- As a Taxpayer
- As a Trading Partner
- As a Distributor

The Industry's Contribution As An Employer . . .

Unlike some American industries in the 1980s, employment among PMA member companies has been growing. In 1985, 312,400 people were employed in the pharmaceutical industry compared to 306,400 in 1980. The pharmaceutical industry has consistently increased the wages of its production workers at a higher rate than the rate of increase in the Consumer Price Index, meaning they receive real growth in their wages.

Index Of Hourly Earnings For Production Workers In The U.S. Pharmaceutical Industry And The Consumer Price Index, 1967–1985 (1967 = 100.0)

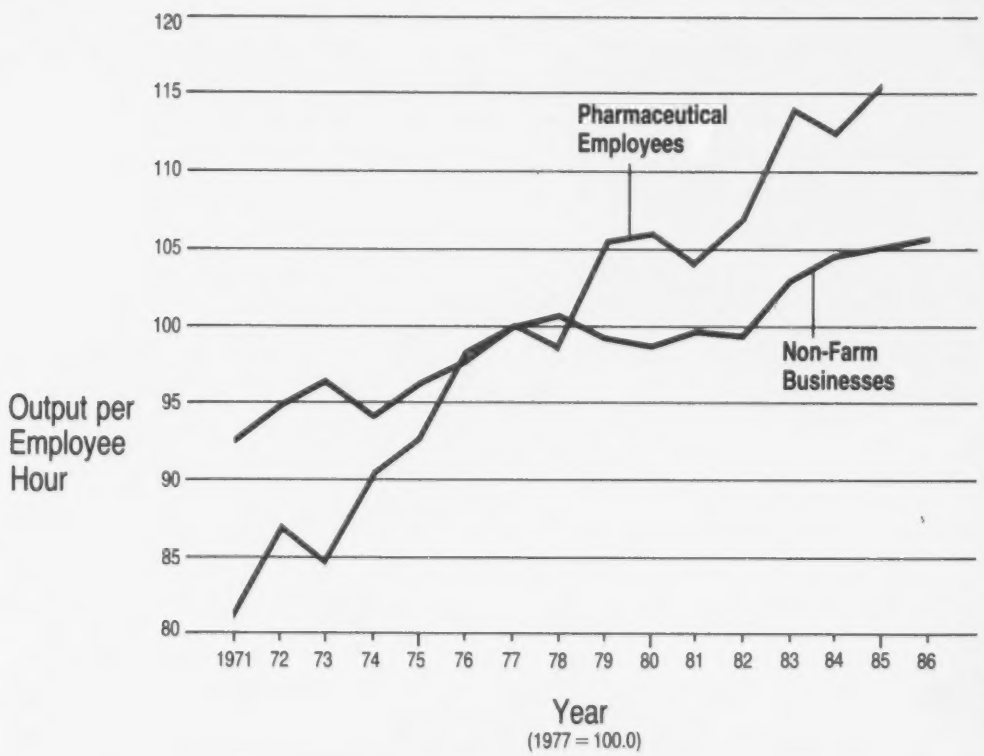


Source: Bureau of Labor Statistics, 1987.

Productive Employees

The pharmaceutical industry's workforce is among the most productive of any industry. As measured by output-per-employee hour, the industry's employees (of whom one out of five work in R&D) increased productivity by 10 percent more than other businesses' employees in 1985.

Employee Productivity

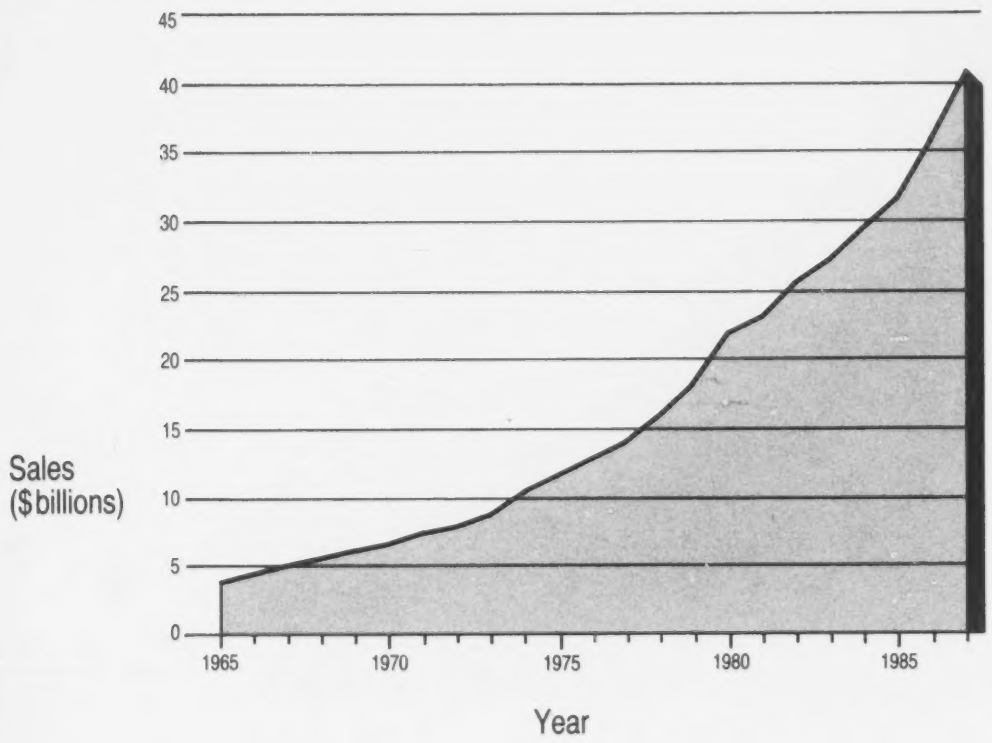


Source: Office of Publications, U.S. Bureau of Labor Statistics, U.S. Department of Labor, (various statistical series).

The Industry's Contribution As A Producer . . .

Total worldwide annual sales of PMA members grew from $4.1 billion in 1965 to $41.2 billion in 1987. While domestic annual sales increased 789 percent, foreign sales grew 1,196 percent for the same period. In 1987, foreign sales represented thirty-five percent of total worldwide sales, compared to one-quarter in 1965.

Worldwide Sales 1965–1987

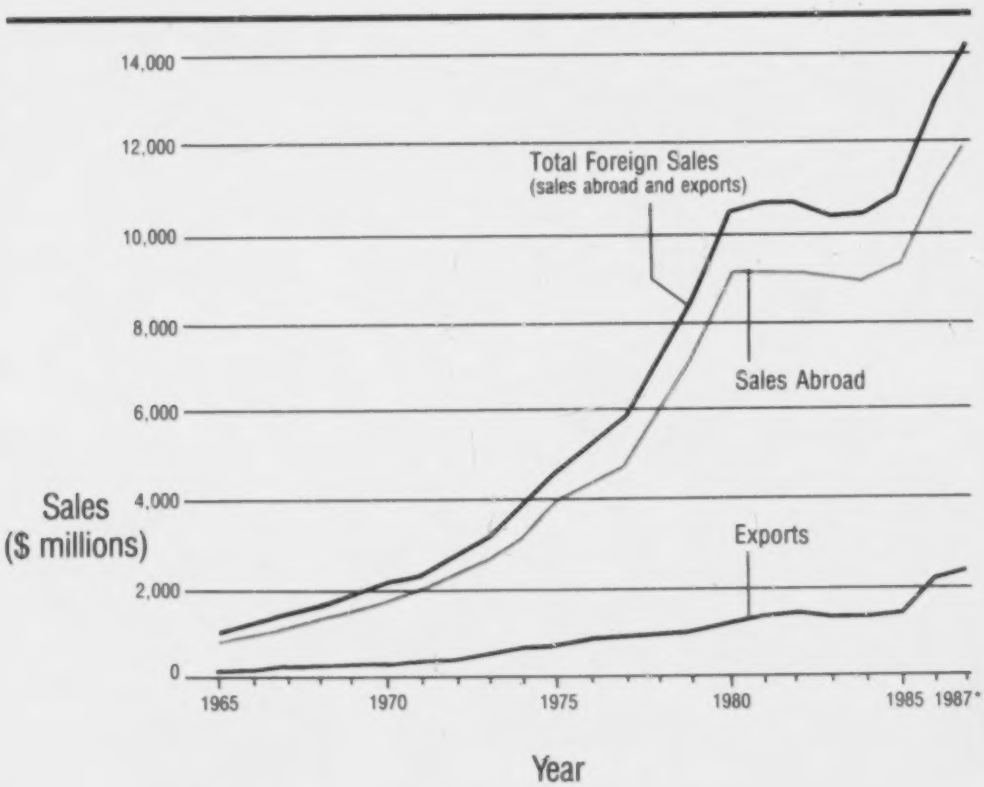


Source: PMA Annual Survey.

A Multi-National Industry

The pharmaceutical industry is multi-national in scope. Many companies have subsidiaries or jointly-owned affiliates in other countries. Many others engage in international operations. Sales of PMA members achieved through manufacturing abroad greatly exceed direct exports from the U.S. In 1987, more than one-third of all sales were sales abroad.

Foreign Sales Of Ethical Pharmaceuticals By U.S.-Owned PMA Member Firms 1965–1987

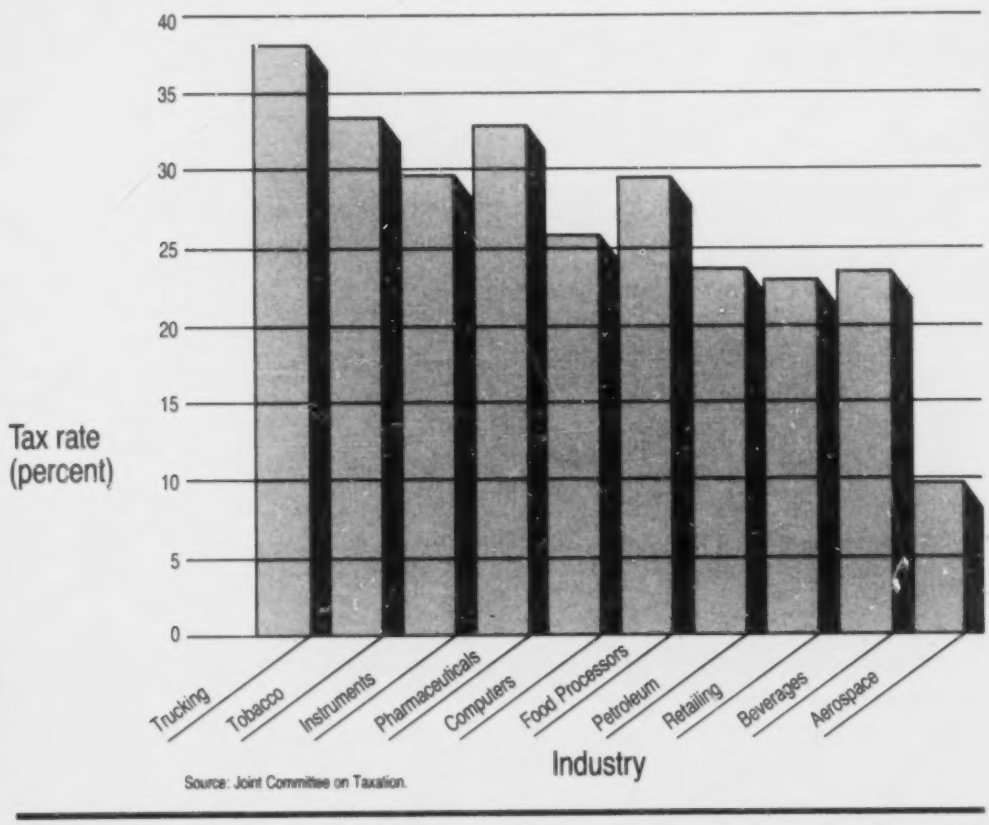


*Estimated.
Source: PMA Annual Survey, various years.

The Industry's Contribution As A Taxpayer . . .

The effective tax rate for the U.S. pharmaceutical industry is among the highest for all industries. Between 1980 and 1983, the average rate for the industry was 32.9 percent, the third highest.

Corporate Effective Tax Rates By Industry 1980–1983 Average

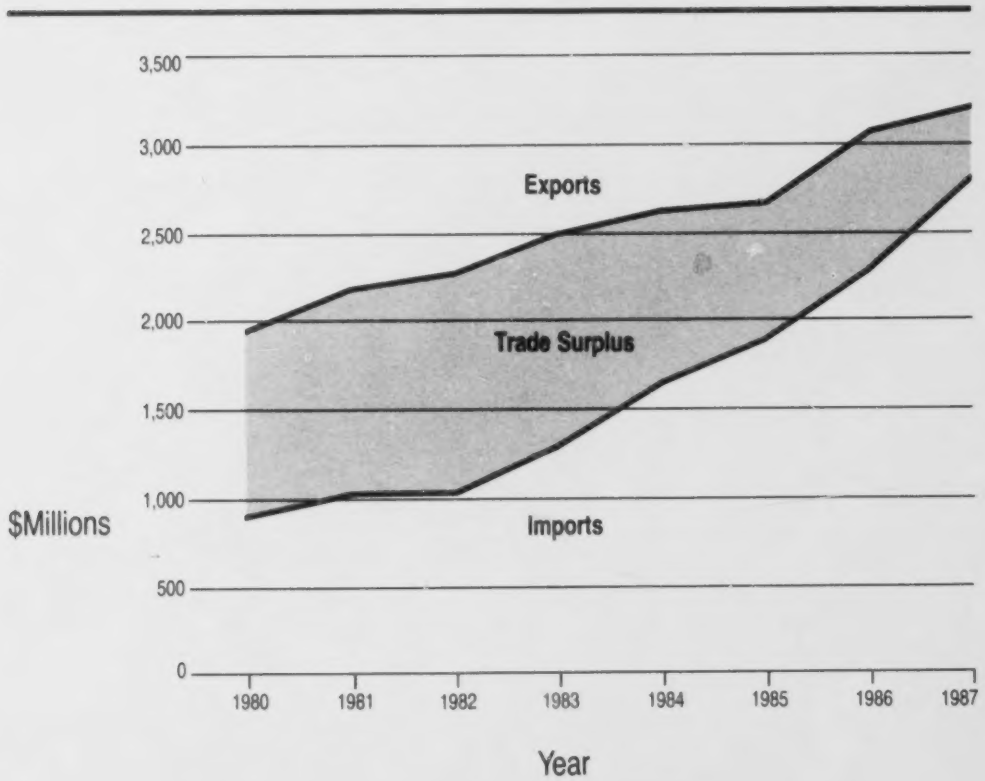


Source: Joint Committee on Taxation.

The Industry's Contribution As A Trading Partner . . .

In a time of national concern about U.S. competitiveness and trade, the U.S. pharmaceutical industry is sustaining a favorable balance of trade. In 1987, the trade *surplus* from pharmaceuticals was $394 million.

Pharmaceutical Industry Trade Balance

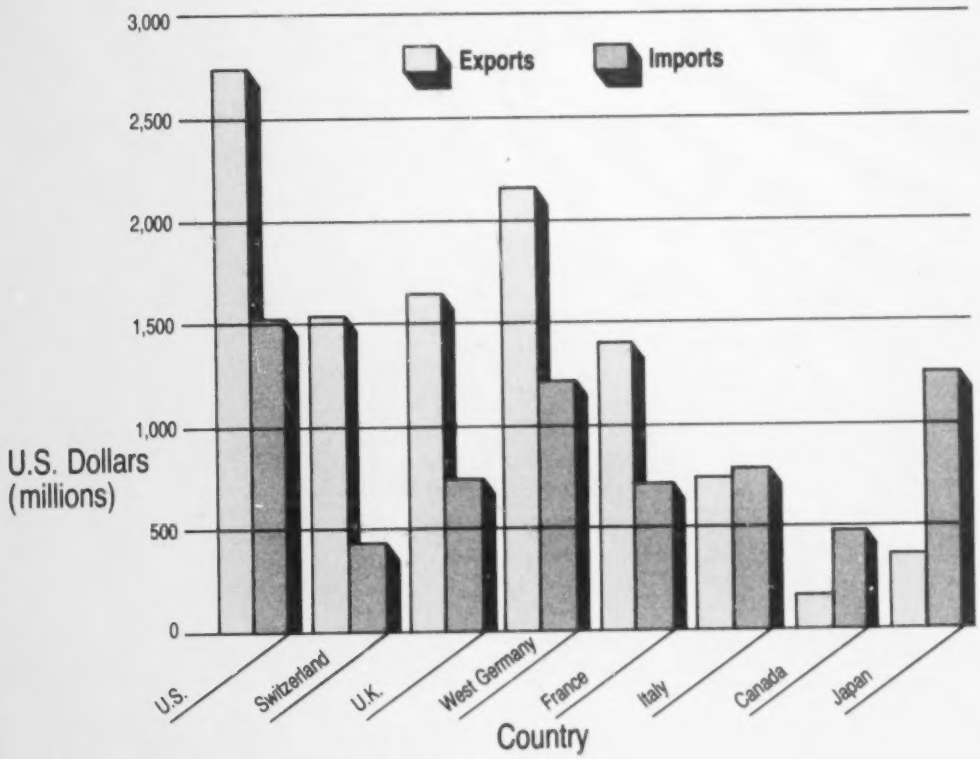


Note: Includes Biologicals; Medicinals and Botanicals; Finished Pharmaceutical Preparations.
Source: U.S. Department of Commerce.

The Leading Exporter And Importer

In 1984, the U.S. became both the leading exporter and importer of pharmaceuticals worldwide. The Federal Republic of Germany, which had been the leading exporter and importer in 1980, is now the second leading exporter. Japan is the second leading importer.

World Trade In Medicinal And Pharmaceutical Products, 1984

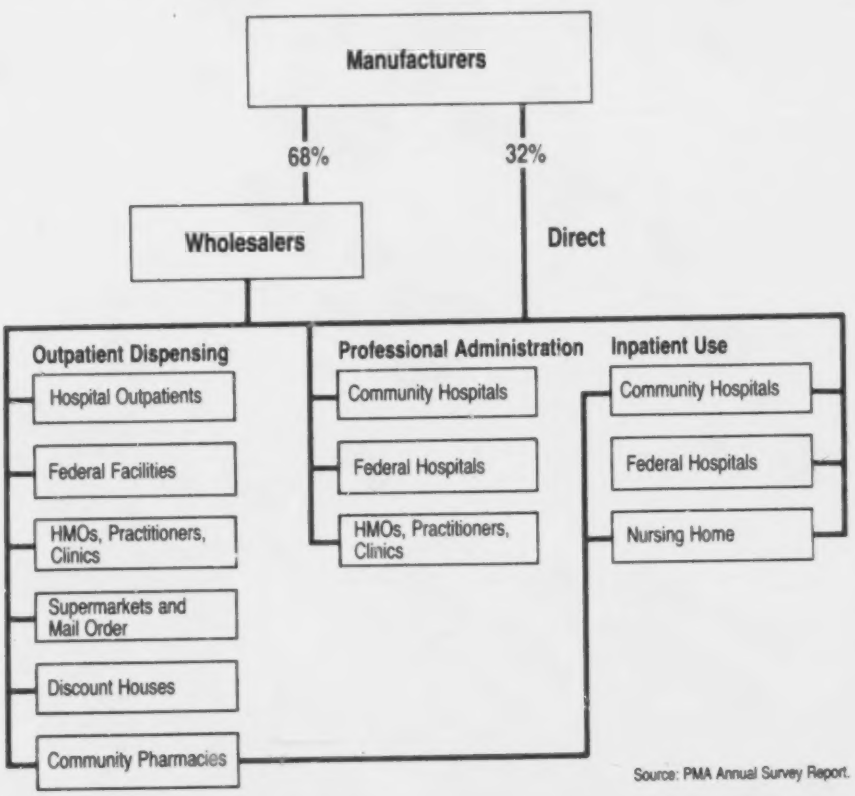


Source: U.N. International Trade Statistics Yearbook.

The Industry's Contribution As A Distributor. . .

The pharmaceutical industry distributes its drug products to consumers through many channels. About 68 percent is distributed through wholesalers to hospitals, HMOs, and retail pharmacies. The remaining 32 percent is sold directly by manufacturers to these outlets.

Channels Of Prescription Drug Distribution

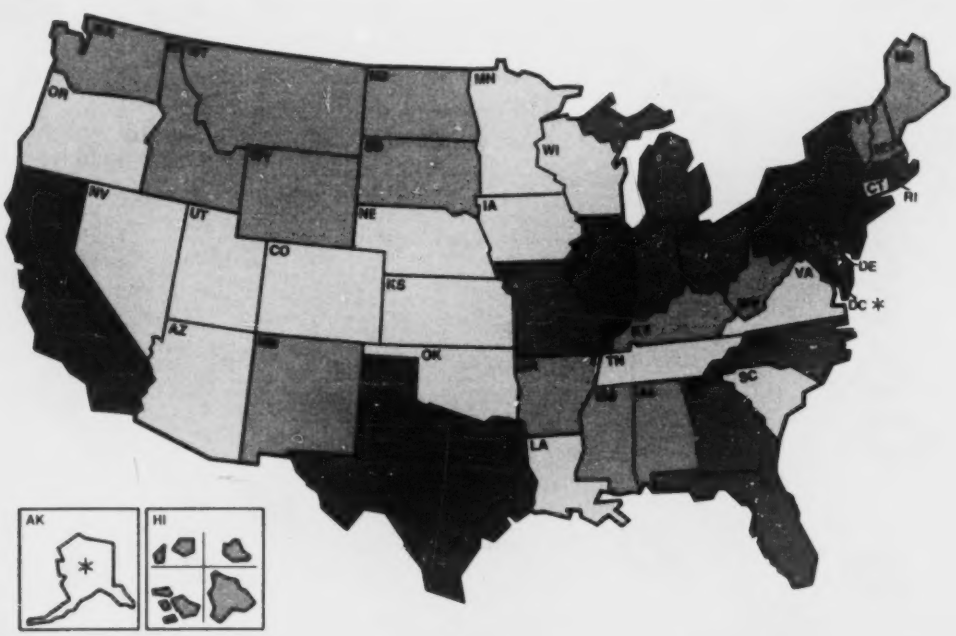


Source: PMA Annual Survey Report.

Industry Facilities Throughout The United States

In the United States, drug industry facilities are located in every state but Alaska, with the concentration in New Jersey, New York, Pennsylvania, Indiana, Illinois, Michigan, Missouri, Ohio, California and Puerto Rico.

Locations For Industry Facilities In The U.S.



Source: U.S. Department of Commerce, Bureau of Census.

II. The Industry's Commitment To Research And Development

The essential characteristic of the research-based pharmaceutical industry is its continued commitment to discovering, developing and marketing major new therapeutic medicines. This mission requires an increasing financial commitment—from $600 million in 1970 to $5.4 billion in 1987.

Innovation in new drug therapy has become significantly more complex, time-consuming and costly over the years. For example:

- It takes an average of 10 years from the time a drug is discovered until it is available to the patient.
- In 1987, the average FDA review time was 32.4 months, two months less than that required for 1986 products.
- It costs well over $100 million to discover and develop a new drug product.
- Approximately 15 percent of U.S. pharmaceutical sales and export revenues was reinvested in research in 1987.

U.S. pharmaceutical companies discover, research and develop most new drug therapies.

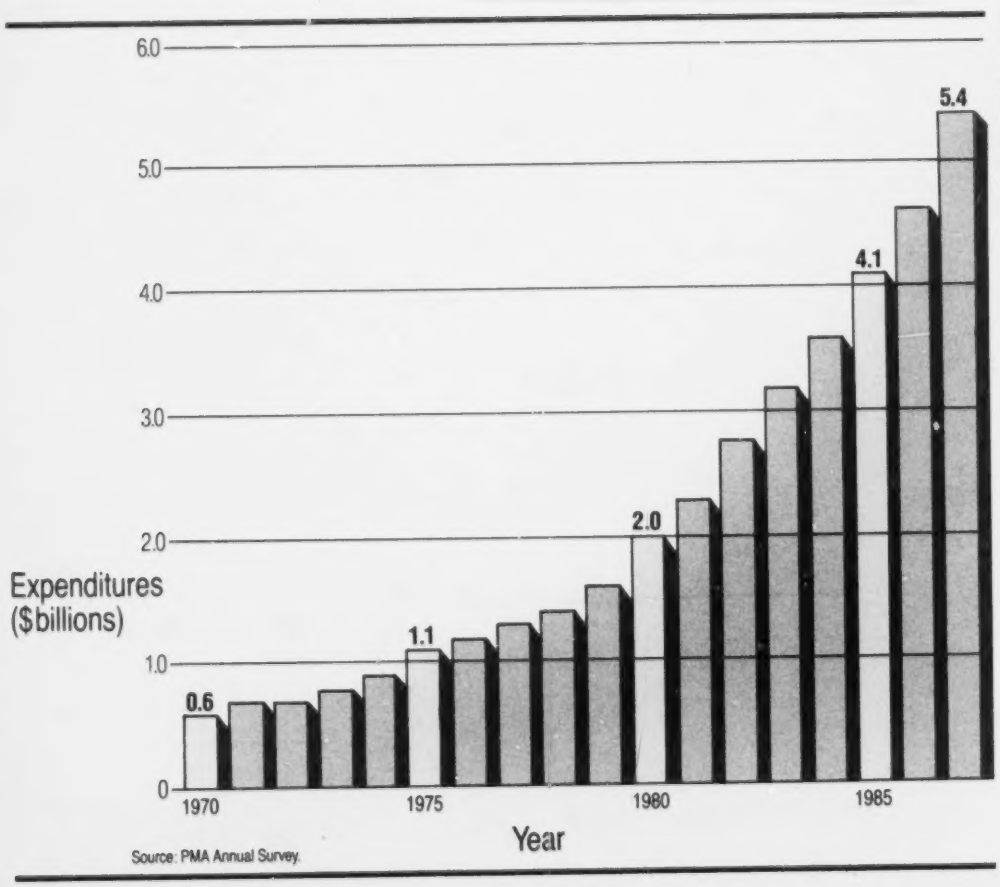
Over 90 percent of the most prescribed drugs in the U.S. was discovered by the research-based pharmaceutical industry.

In the last four decades, the industry has produced a wide range of therapeutic products. It has now turned to biotechnology and other new technologies to continue to pursue new avenues for drug innovation.

Major Research Commitment —R&D Expenditures

In 1987, the research-based pharmaceutical companies invested a record $5.4 billion in research and development, an increase of 14.9 percent from 1986. This research commitment has been growing at a rate of more than 10 percent a year. The industry's research investment has doubled every five years since 1970.

R&D Expenditures For PMA Member Firms

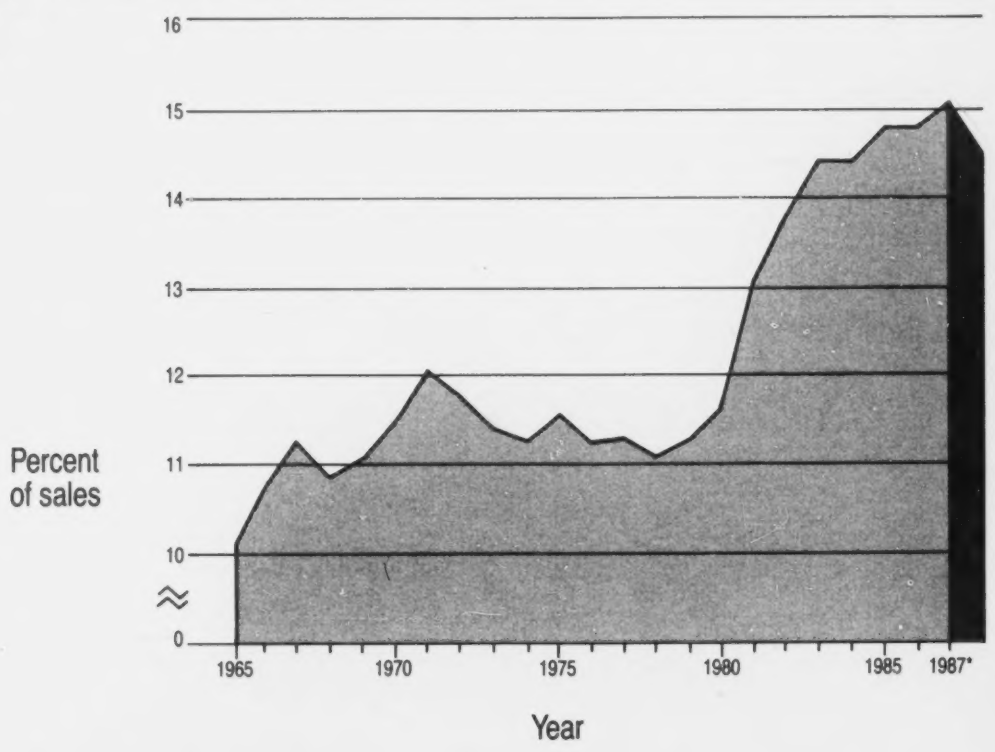


Source: PMA Annual Survey.

Research Spending—A High Percentage Of Sales

In 1987, 15 percent of U.S. pharmaceutical sales and export revenues were reinvested in research —up from 11.3 percent ten years earlier. During the 1980s alone, the portion of sales revenues reinvested into R&D increased by more than 29 percent.

R&D Expenditures As A Percentage of Sales 1965—1987

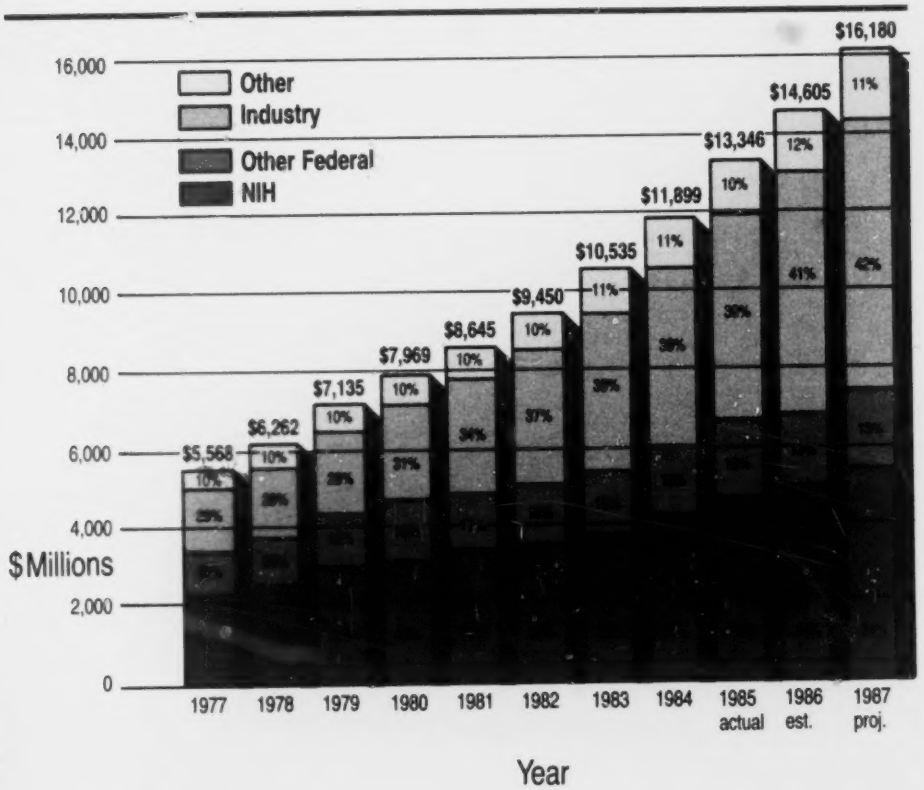


*Estimated
Source: PMA Annual Survey.

A Major Source Of Medical Research

Private industry's investment in medical research and development now outstrips the amount committed by the National Institutes of Health. In 1987, 42 percent of total spending for biomedical R&D in the U.S. was invested by industry compared with 34 percent by the National Institutes of Health. The research-based pharmaceutical industry's investment of $5.4 billion in 1987 nearly matches the $5.8 billion appropriations for NIH health research.

National Support For Health R&D By Source, 1977—1987



Source: National Institutes of Health.

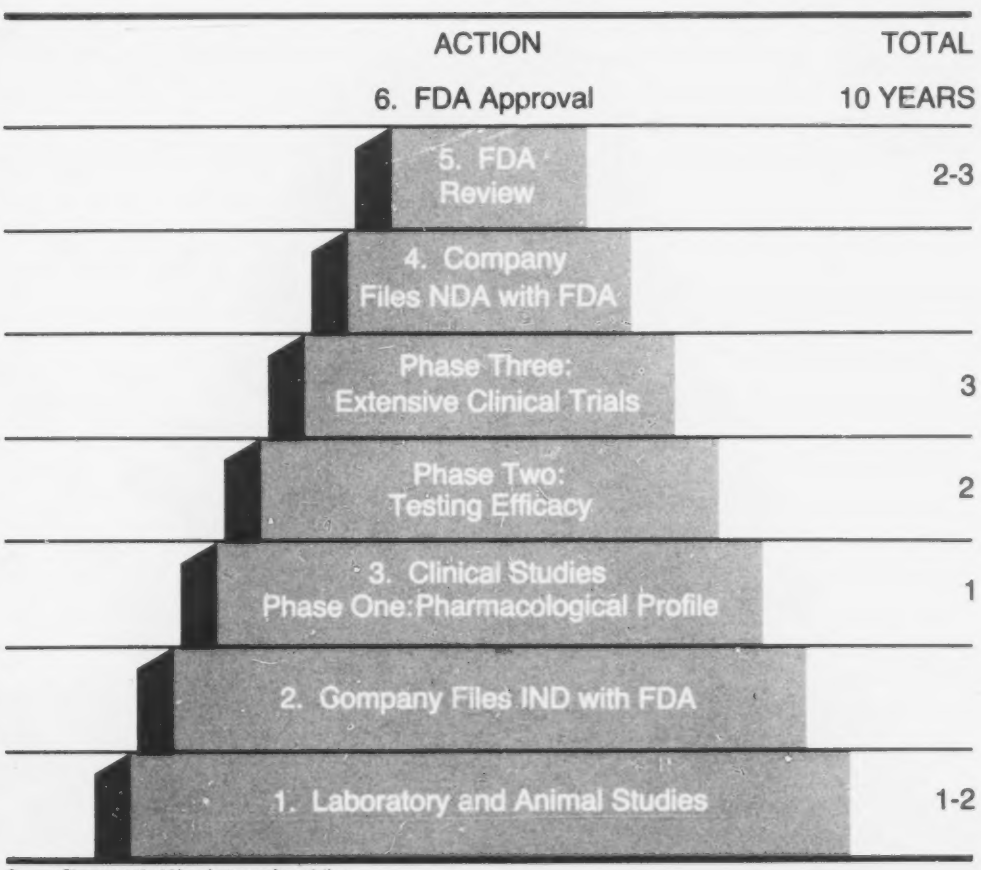
The High Cost Of Drug Development

On average, it costs well over $100 million to bring a new drug through discovery, clinical testing, development and FDA approval to begin marketing. This cost has increased sharply in recent years. Major contributors to the increased cost include the intricate nature of modern research and the expense of the highly sophisticated laboratory equipment it requires. In addition, as the focus of research has shifted toward chronic and degenerative diseases, complicated and extensive clinical testing is often necessary to prove efficacy of new medicines.

A Decade From Discovery To Marketing

It takes approximately one decade from the time that the new drug is discovered until it is available to the patient in a pharmacy or hospital.

The Steps Toward Drug Approval

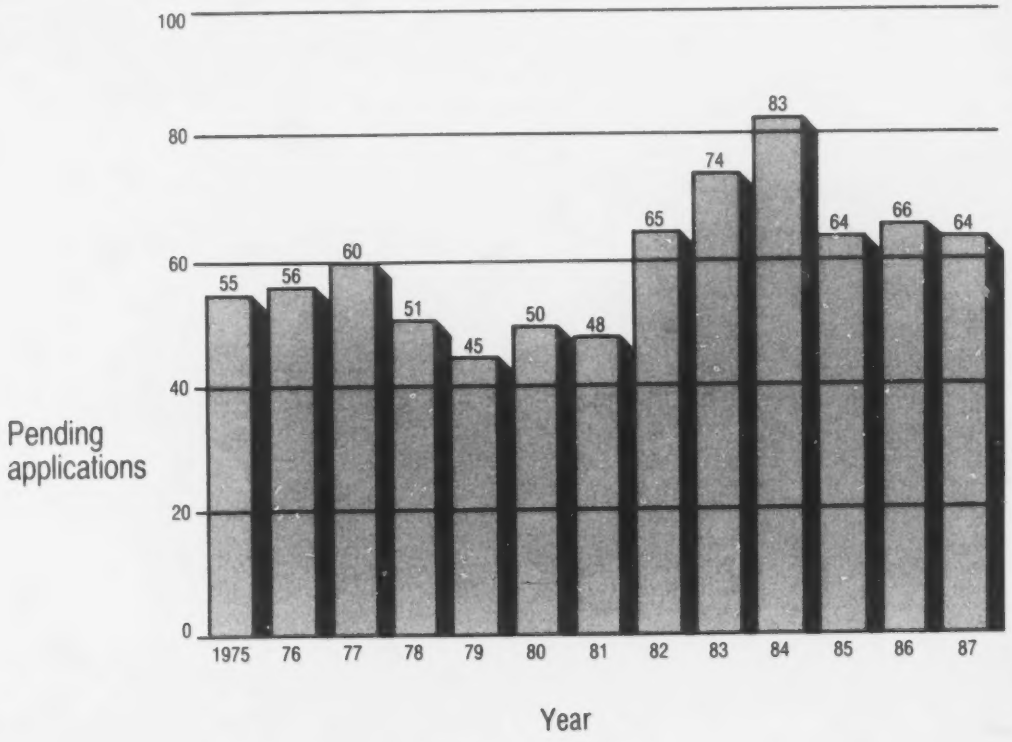


Source: Pharmaceutical Manufacturers Association

FDA Backlog On The Rise

FDA's workload and backlog for new drug applications has increased.

NME Backlog

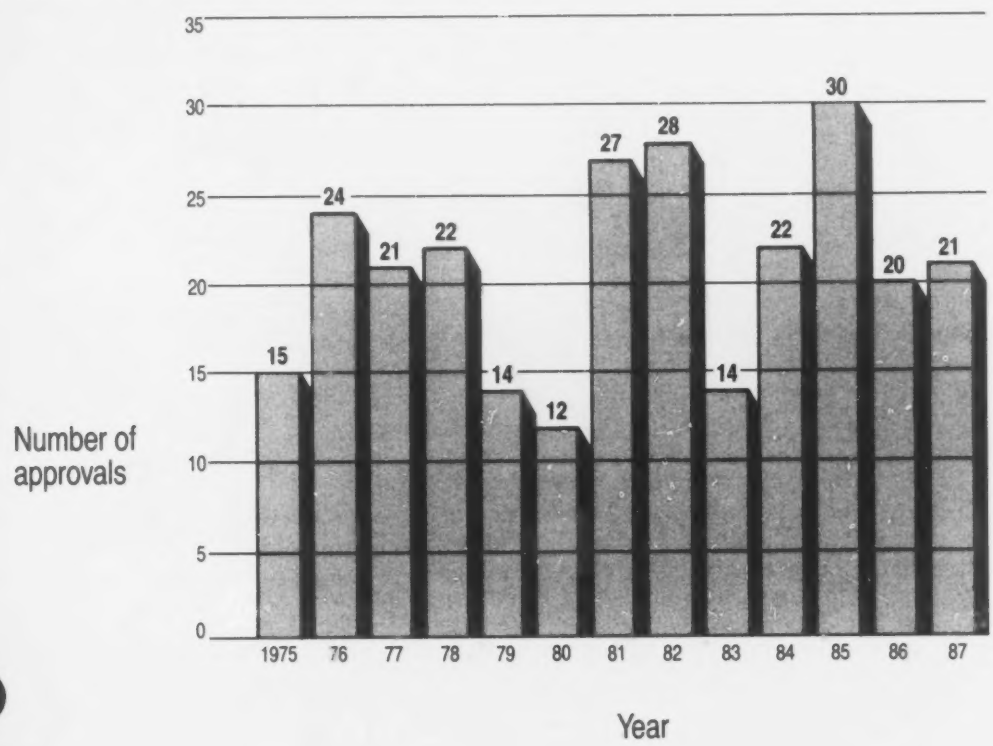


Source: U.S. Food and Drug Administration

FDA New Drug Approvals

The FDA approved 21 new drugs (new molecular entities or NMEs) in 1987, up from 20 approved in 1986.

U.S. NME Approvals Per Year



Source: U.S. Food and Drug Administration.

New Drugs Approved In 1987

The 21 drugs approved by the FDA in 1987 include the following: .

New Drugs Approved In 1987

NAME	MANUFACTURER	CATEGORY
	Drugs (New Molecular Entities)	
Bactroban	Beecham	Antibiotic
Cefmax	Tap Pharm.	Antibiotic
Choletec	Squibb	Radioactive diagnostic
Cipro	Miles	Antimicrobial
Deursil	Gipharmex S.P.A./Ciba Geigy	Dissolution of gallstones
Elocon	Schering	Corticosteroid
Hytrin	Abbott	Antihypertensive
Iopidine	Alcon	Opthalmic surgery; prevent intraocular pressure spikes
Levatol	Eli Lilly	Beta blocker
Milrinone lactate*	Sterling	Congestive heart failure
Novantrone	Lederle	Antineoplastic

Source: U.S. Food and Drug Administration

New Drugs Approved In 1987

NAME	MANUFACTURER	CATEGORY
	Drugs (New Molecular Entities)	
Parathar	Rorer	in vivo diagnostic; hypoparathyroidism
Prinivil	Merck	Antihypertensive
Prozac	Eli Lilly	Antidepressant
Retrovir	Burroughs Wellcome	Antiviral
Rimadyl	Hoffmann-la Roche	Antiarthritic
Rowasa	Reid-Rowell	Ulcerative colitis
Spectamine	Medi-Physics	in vivo diagnostic
Terazol 7	Ortho	Vulvovaginal candidiasis
Ucephan	Kendall McGaw	Urea metabolism disorders

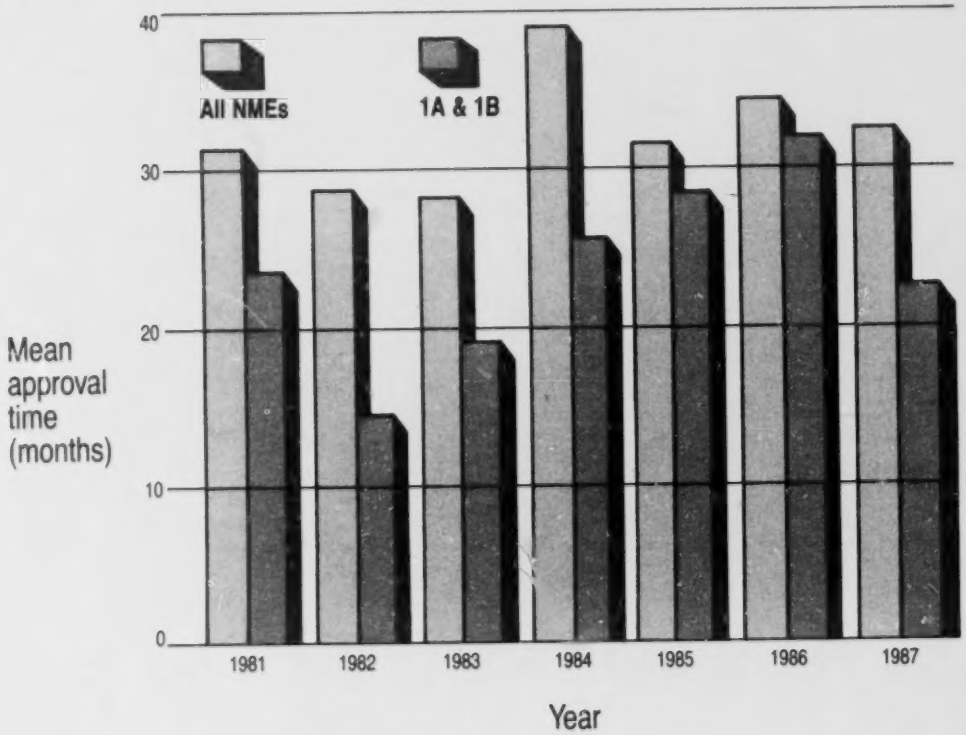
*generic name

Source: U.S. Food and Drug Administration

A Long Review Process

The average FDA review time for the 21 new molecular entities approved in 1987 was 32.4 months, almost two months shorter than that required for 1986 products. Shown below are mean review times since 1981 for all NMEs and for NMEs rated 1A and 1B ("fast track" drugs representing FDA assessments of therapeutic gains.)

Mean Approval Times 1981—1987

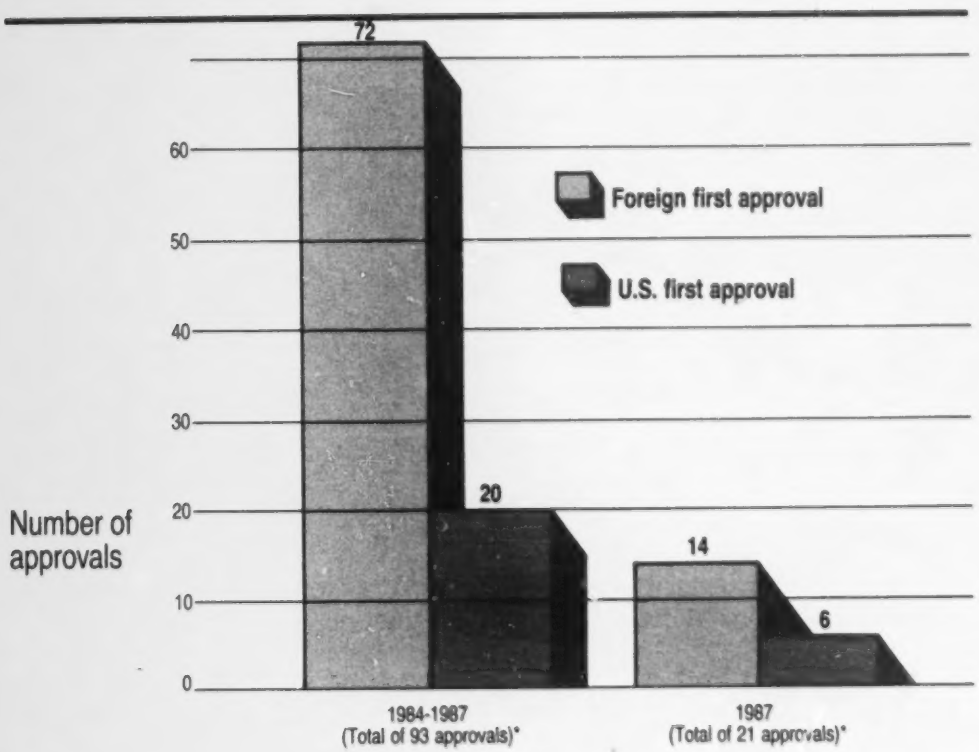


Source: U.S. Food and Drug Administration.

New Drugs Often Approved Overseas First

Of the 93 new molecular entities approved by the Food and Drug Administration between 1984 and 1987, 72 were first approved in a foreign country, a trend that has become common in recent years. It should be noted that companies often seek approval for their products first in foreign countries.

NMEs Marketed Abroad Prior To U.S. Approval (1984—1987)



*One NME approved in 1987 has not yet been marketed anywhere, although it was first approved abroad.

Source: PMA Survey.

FDA Approval Lags Behind Foreign Marketing

Over the past four years (1984-1987), more than half of the 72 drugs already approved abroad were available in at least four countries at the time of FDA approval. The average lag time between first foreign marketing and FDA approval for the 72 products was 5.7 years.

U.S. NME Approvals Country Of First Approval

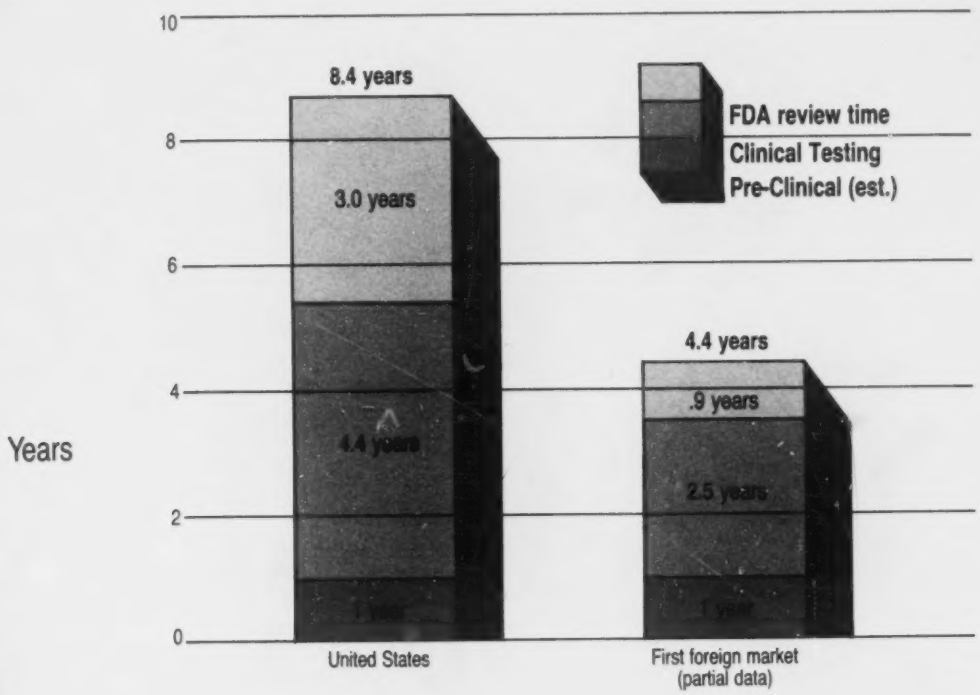
Total NMEs	72
Germany	53
United Kingdom	39
Switzerland	38
France	31
Italy	31
Japan	21
Canada	14
Sweden	9
Belgium	12
Netherlands	4

Source: PMA Survey

Average Drug Development Times Longer In The U.S. Than Abroad

For those 1987 products first approved overseas, the average review time was 0.9 year. compared with a mean review time of 36 months taken by the FDA for those same products. Average development times for these 14 products in the first foreign market and the U.S. are compared below.

Average Development Time 1987 NMEs First Approved Abroad



Source: PMA Survey.

U.S. Companies Lead In Drug Discovery

Between 1940 and 1987, 1198 drugs were introduced in the U.S. market. Nearly 62 percent was discovered in the U.S.

New Single Chemical Entity Drugs Introduced To U.S. Market 1940—1987, By Country Of Origin

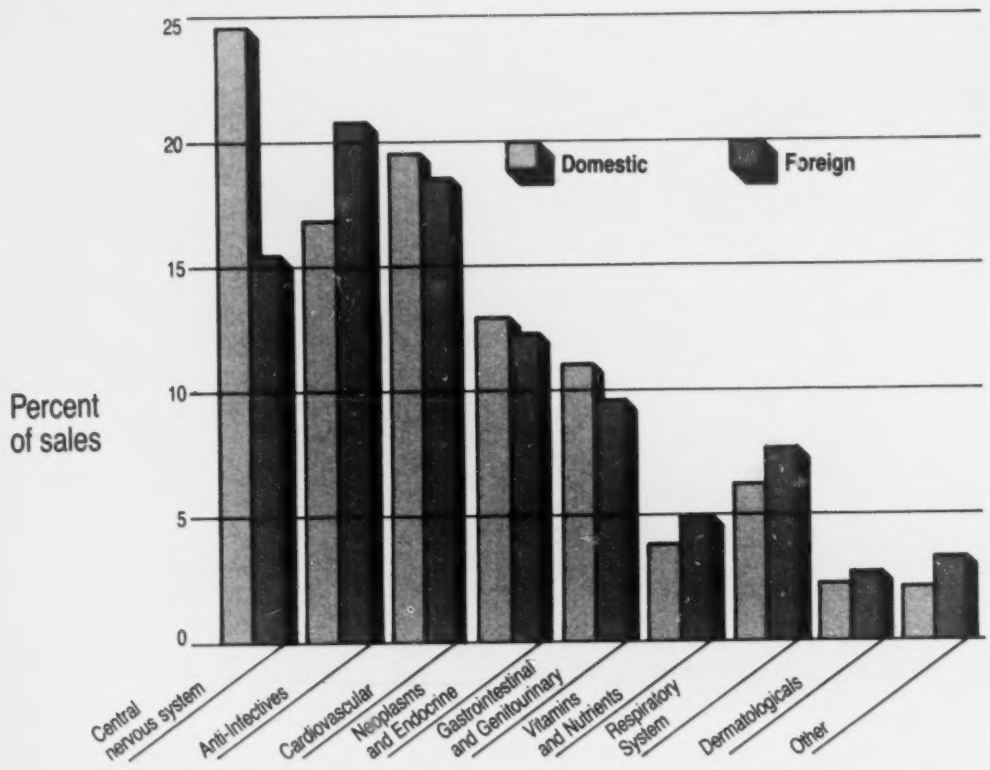
COUNTRY OF ORIGIN	PERCENTAGE OF TOTAL 1,198 NEW DRUGS
United States	61.5%
Switzerland	6.8%
United Kingdom	6.2%
West Germany	5.5%
France	3.2%
Japan	1.7%
Denmark	1.5%
Belgium	1.6%
Sweden	1.4%
Holland	1.3%
Italy	1.0%
Mexico	.8%
Austria	.3%
Canada	.3%
Australia	.2%
Hungary	.2%
Czechoslovakia	.1%
Argentina	.1%
India	.1%
Other	6.2%
TOTAL	100%

Source: PMA Analysis of Paul De Haen data

A Wide Range Of Therapies

The pharmaceutical industry produces drugs in many therapeutic categories. In the U.S., central nervous system products are the leading category. Abroad, anti-infectives are the leading sellers.

PMA Member Firms Domestic And Foreign Sales Of Ethical Drugs For Human Use

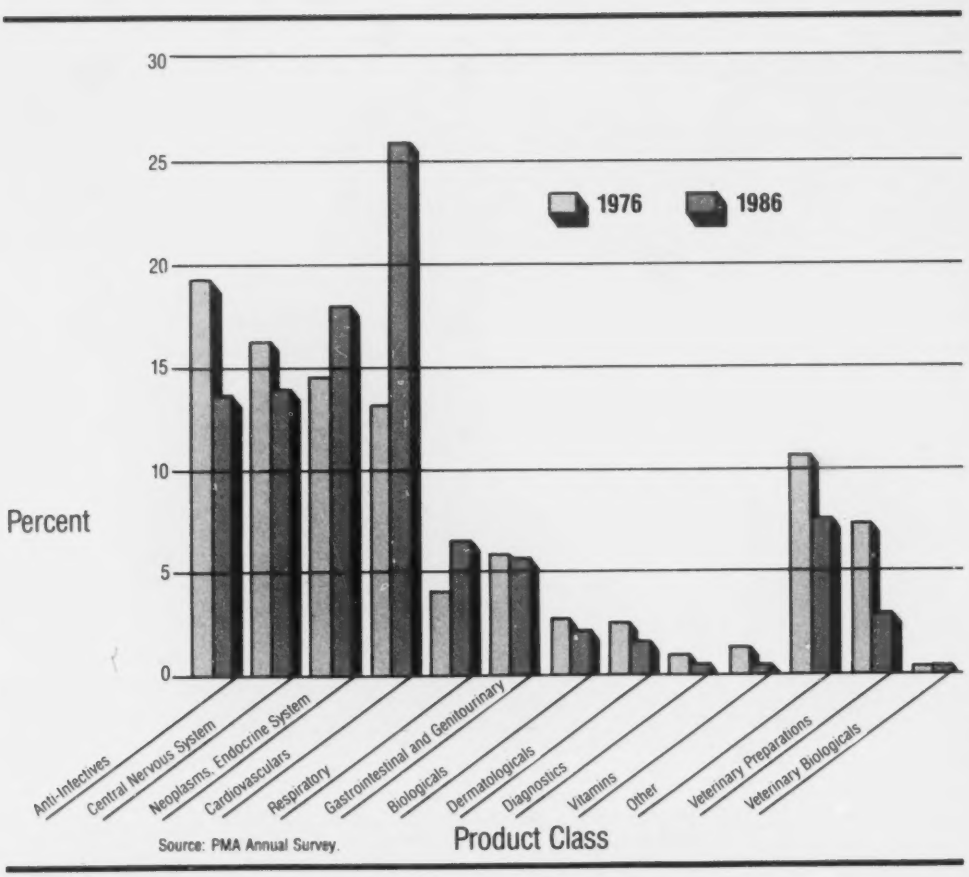


Source: PMA Annual Survey.

Shift In The Types Of Drugs Being Developed

The focus of industry R&D has changed significantly in the last 10 years. In 1976, 19.5 percent of R&D went to anti-infectives while 13.2 percent was for cardiovascular products. In 1986, R&D for anti-infectives dropped to 13.9 percent while cardiovascular R&D rose to 25.8 percent.

U.S. R&D, 1976 And 1986

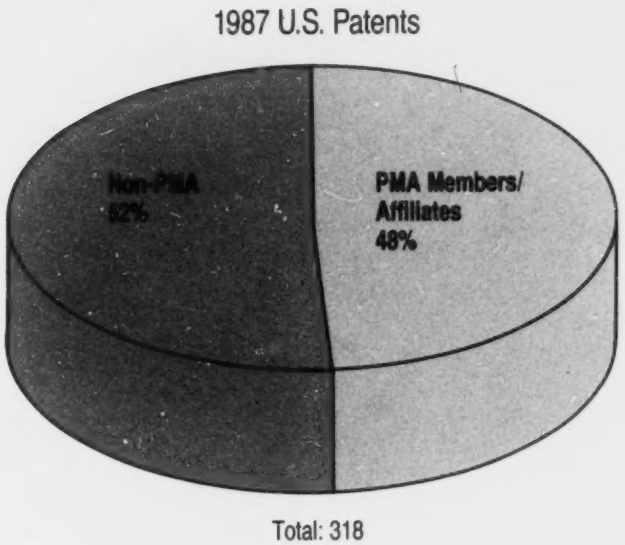


Source: PMA Annual Survey.

The New Research Challenge: Biotechnology

Biotechnology is opening major new avenues for drug innovation. The U.S. Patent Office issued 1,476 biotechnology-related patents in 1987, of which more than half were pharmaceutical- or health-related. PMA members were issued 48 percent of the pharmaceutical- or health-related patents issued to U.S. corporations.

U.S. Corporate Pharmaceutical/ Health Care Biotechnology Patent Ownership



Source: OMEC International, Inc.

III. The Value Of Pharmaceuticals In Improving Health Care And In Reducing The Costs Of Illness

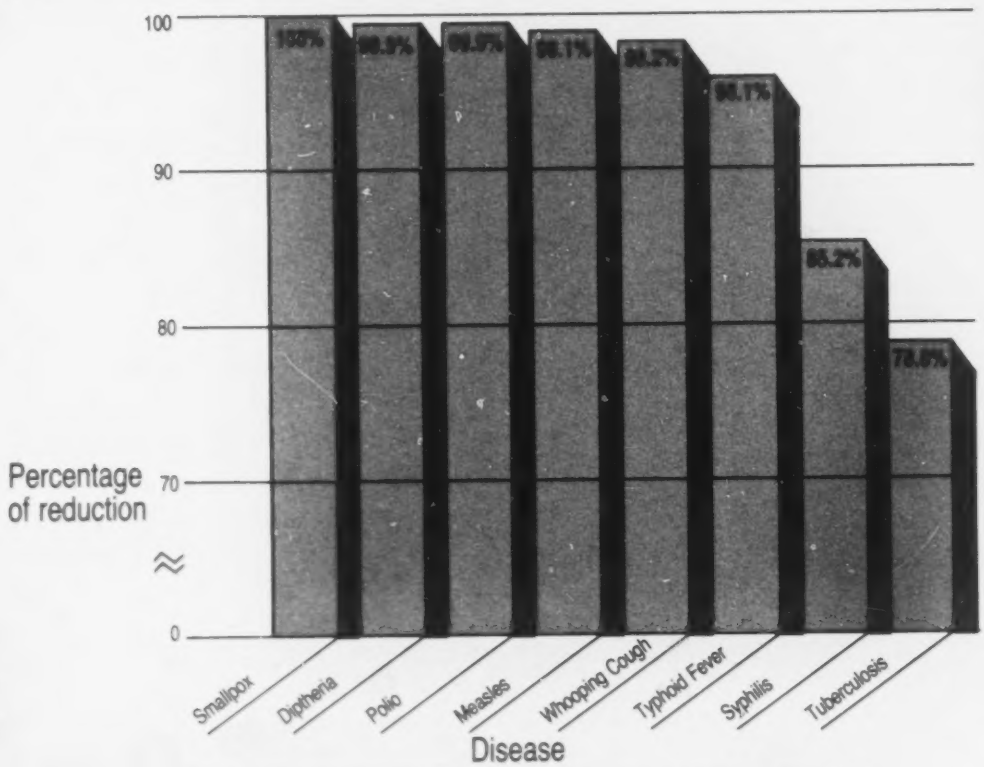
Among the most important technological advances of the Twentieth Century are those that have strengthened our ability to conquer disease and have extended the length and enhanced the quality of human life.

Medicines discovered and developed by the research-based pharmaceutical industry have yielded dividends in both lives and dollars saved.

Medicines have contributed significantly to the reduction of disease. Medicines have virtually eliminated diphtheria and polio.

Improved Health: Reduced Morbidity

Reduction In Reported U.S. Cases Of Selected Diseases 1940–1985

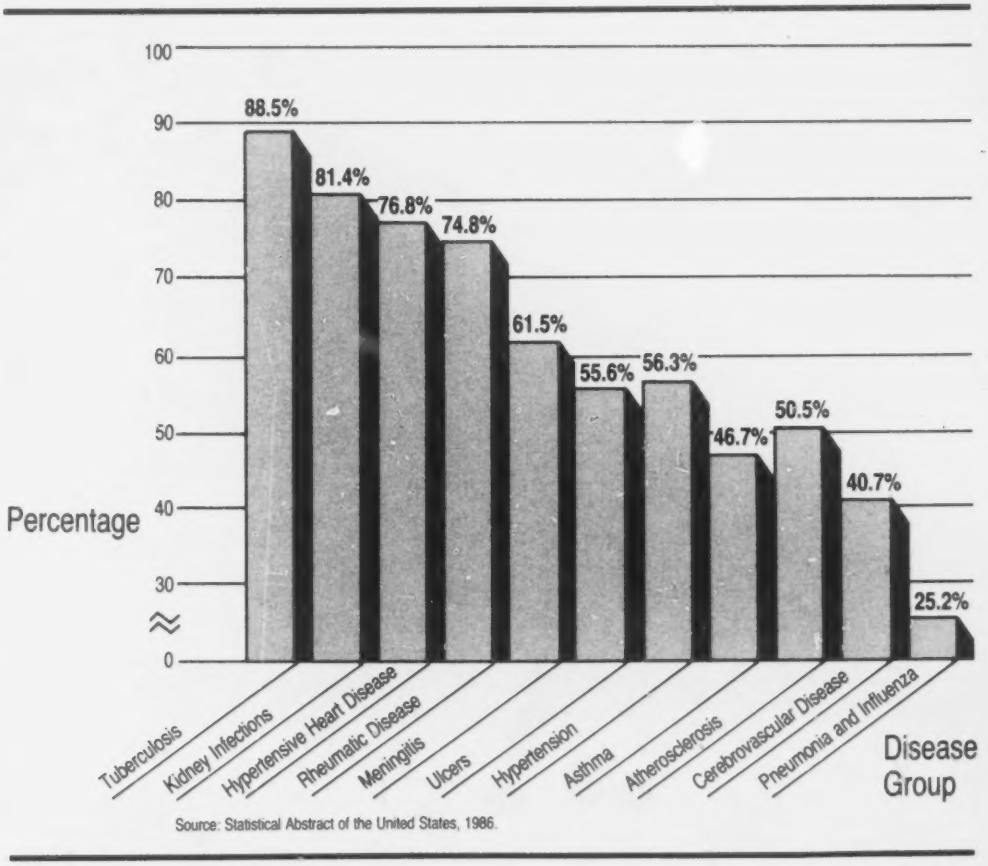


Source: Morbidity and Mortality Weekly Report, Annual Summary, 1984, U.S. Dept. of Health and Human Services.

Improved Health: Reduced Mortality

Pharmaceuticals have helped reduce deaths from diseases such as tuberculosis, kidney infection and hypertensive heart disease.

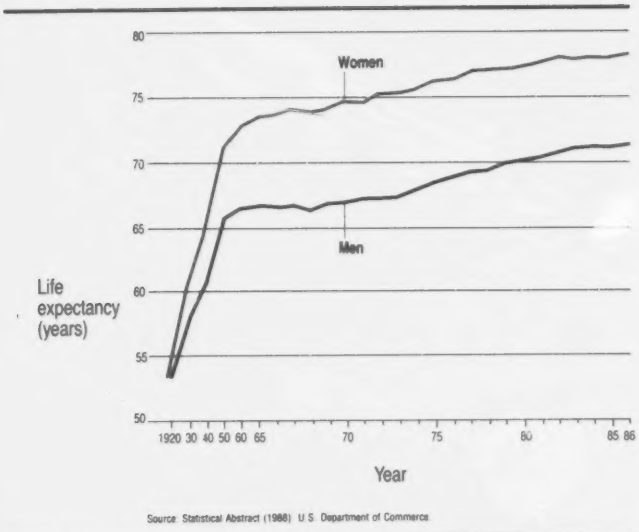
Mortality: Reduction In U.S. Deaths Per 100,000 Population From Selected Diseases 1960–1985



Source: Statistical Abstract of the United States, 1986.

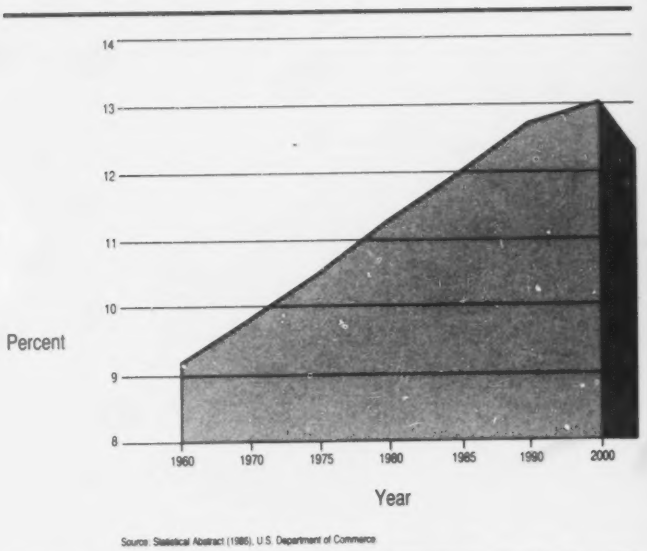
Improved Health: Increased Life Expectancy

New medicines have helped increase life expectancy. The average life expectancy for a person born in 1920 was 54.1 years, compared to 74.9 years today. The percent of people 65 years and older is increasing dramatically and will continue to do so through the end of the century.



Source: Statistical Abstract (1988), U.S. Department of Commerce

U.S. Expectation Of Life At Birth 1920–1986



Source: Statistical Abstract (1988), U.S. Department of Commerce

Over-65 Population As A Percent Of U.S. Population 1960–2000

Economic Benefits

Drugs not only reduce sickness and save lives, they also save money. They usually represent the least expensive form of health care. For example:

- Use of beta-blockers to prevent second heart attacks may save $1.6 billion to $3 billion per year.
- Medicaid expenditures for patients using an anti-ulcer drug have been shown to be about 70 percent less than for patients not using the drug.
- The use of antibiotics to prevent urinary tract infections reduces costs 33 percent per patient.
- For people with mild to moderate heart disease, the savings of using drugs over coronary bypass surgery is estimated at $500 million a year.
- Beta-blockers have saved as much as $1 billion annually when compared to the surgical alternative.

IV. Today's Health Care Environment

The changing health care environment greatly affects the research-based pharmaceutical industry.

Today's health care system has to deal with a different population—an older one—due in part to advances made by the pharmaceutical industry.

As a result of the growing population, inflation, and spiraling costs, national health expenditures continue to rise. So do per capita health care expenditures and health expenditures as a percentage of the GNP. By contrast, drugs as a percent of national health expenditures have steadily declined.

As cost-containment strategies are initiated it is important to remember that drugs represent a small percentage of national and Medicaid expenditures and can help to reduce the total costs of health care.

Health Care Labor Force

The number of people employed in the health care industry has grown from 4.2 million in 1970 to 7.9 million in 1984, an increase of more than 85 percent. Registered nurses form the largest health occupation group (1.4 million workers) followed by nursing aides (1.2 million).

U.S. Health Industry Personnel, Selected Categories

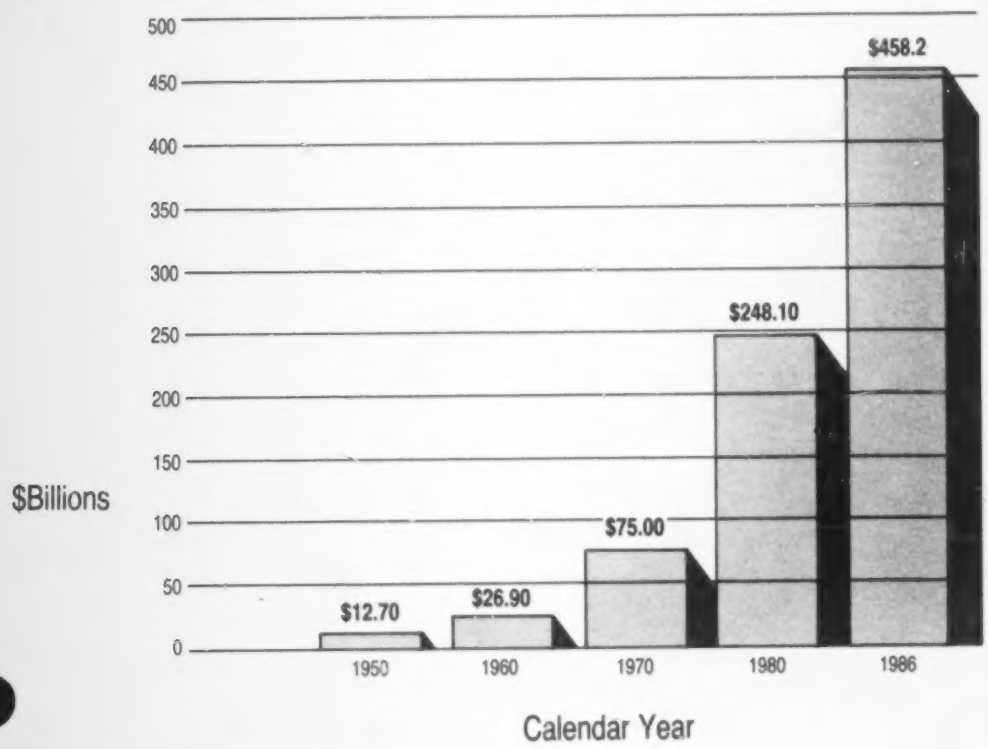
OCCUPATION	PERSONNEL
Doctors of Medicine	504,000 (a)
Doctors of Osteopathy	21,000 (a)
Dentists	163,000 (a)
Pharmacists	158,000 (a)
Health Technologists and Technicians	1,112,000 (b)
Optometrists	18,000 (a)
Physician Assistants	43,000 (b)
Registered Nurses	1,402,000 (b)
Practical Nurses	416,000 (b)
Nursing Aides	1,235,000 (b)
Managers, Medicine and Health	96,000 (b)

Source: (a) Business Mailers, 1986 data and (b) *1986 Statistical Abstract of U.S.*, 1984 data

National health expenditures have been doubling or tripling every decade.

National Health Expenditures On The Rise

National Health Expenditures (Current Dollars)

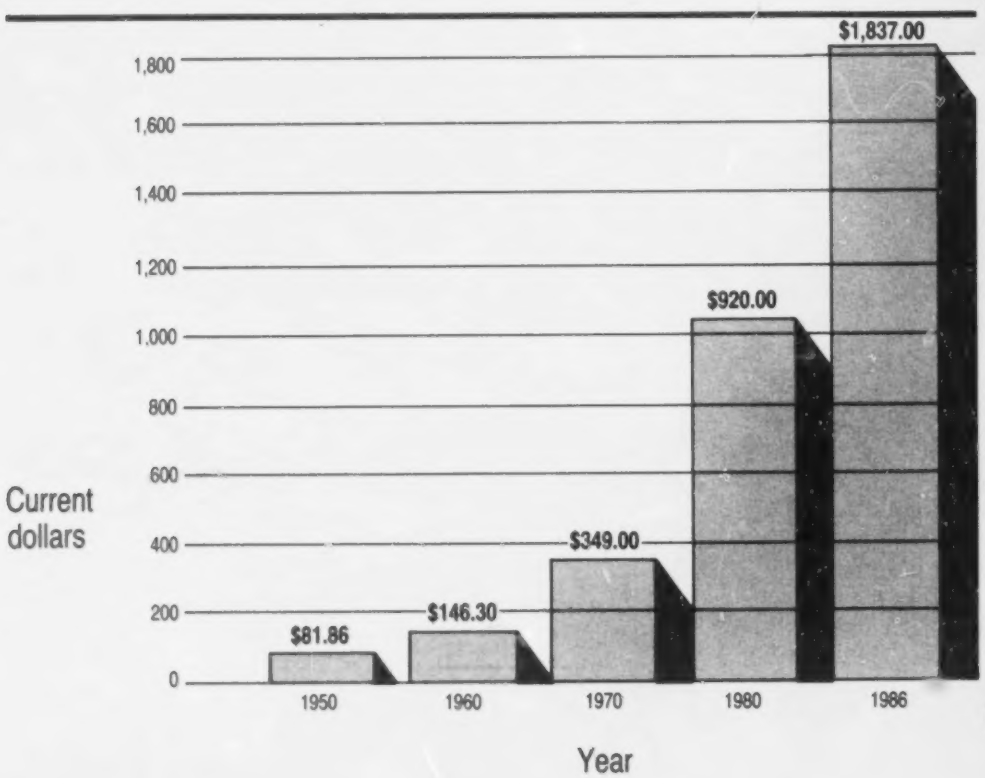


Source: Health Care Financing Administration.

Per Person Expenditures On The Rise

Average per person health care expenditures have also been increasing steadily.

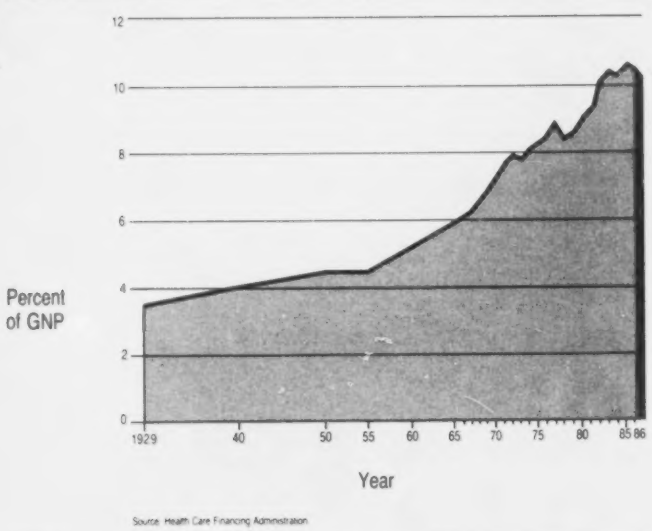
Per Capita National Health Expenditures



Source: Health Care Financing Review.

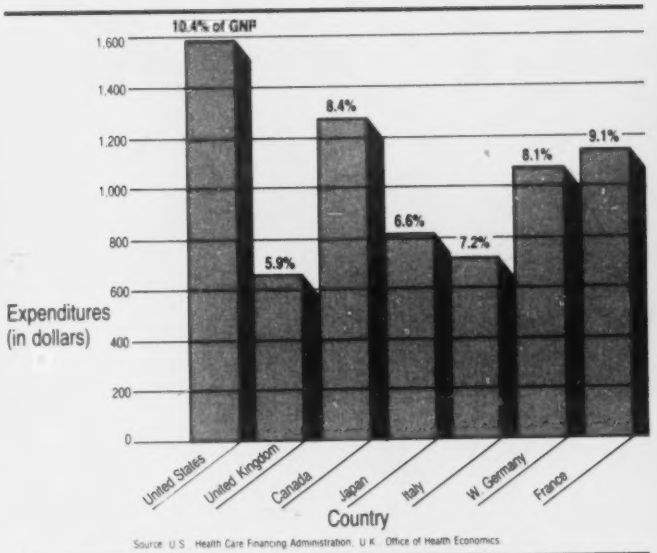
Health Expenditures As Percent Of GNP On The Rise

More of the nation's GNP is going to health care. The U.S. is the world leader in per capita spending and percent of GNP spent for health.



Source: Health Care Financing Administration

National Health Expenditures As Percent Of GNP Calendar Years 1929 – 1986



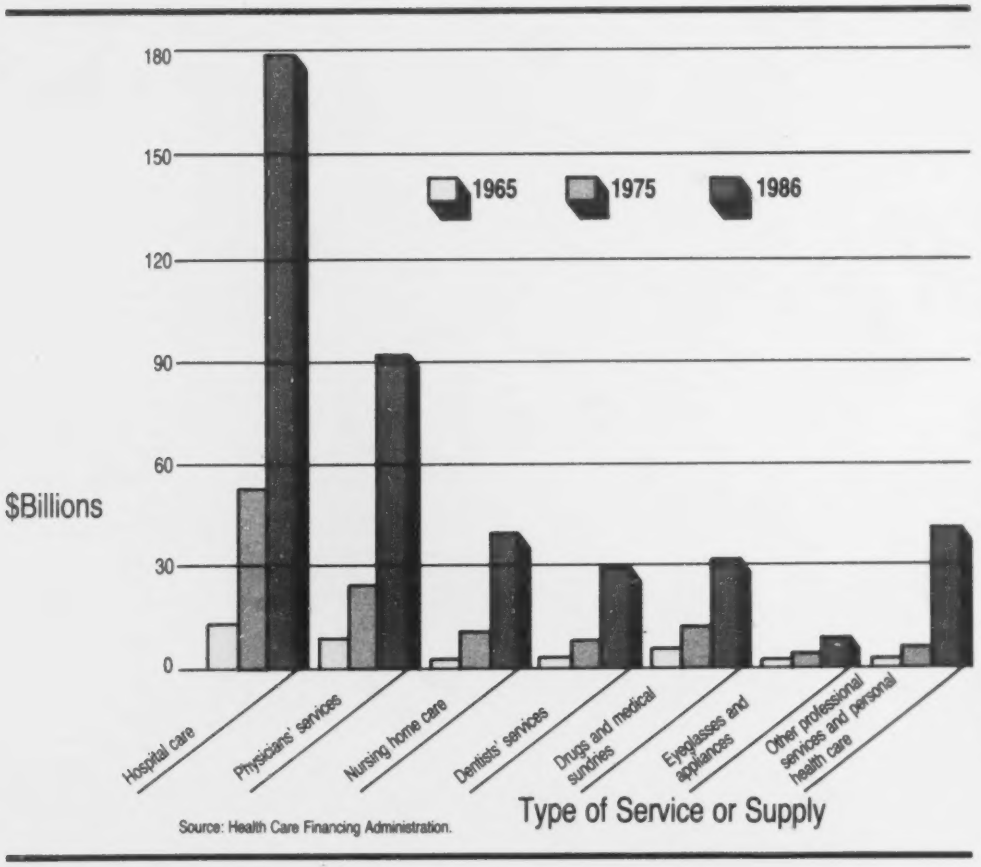
Source: U.S. Health Care Financing Administration, U.K. Office of Health Economics

International Comparisons Of Per Capita Health Expenditures 1984

The Breakdown Of Health Care Expenditures

Hospital care represents the largest proportion of expenditures and in 1986 accounted for 39.2 percent of all health costs. The next largest component was for physicians (20.1 percent).

Personal Health Care Expenditures

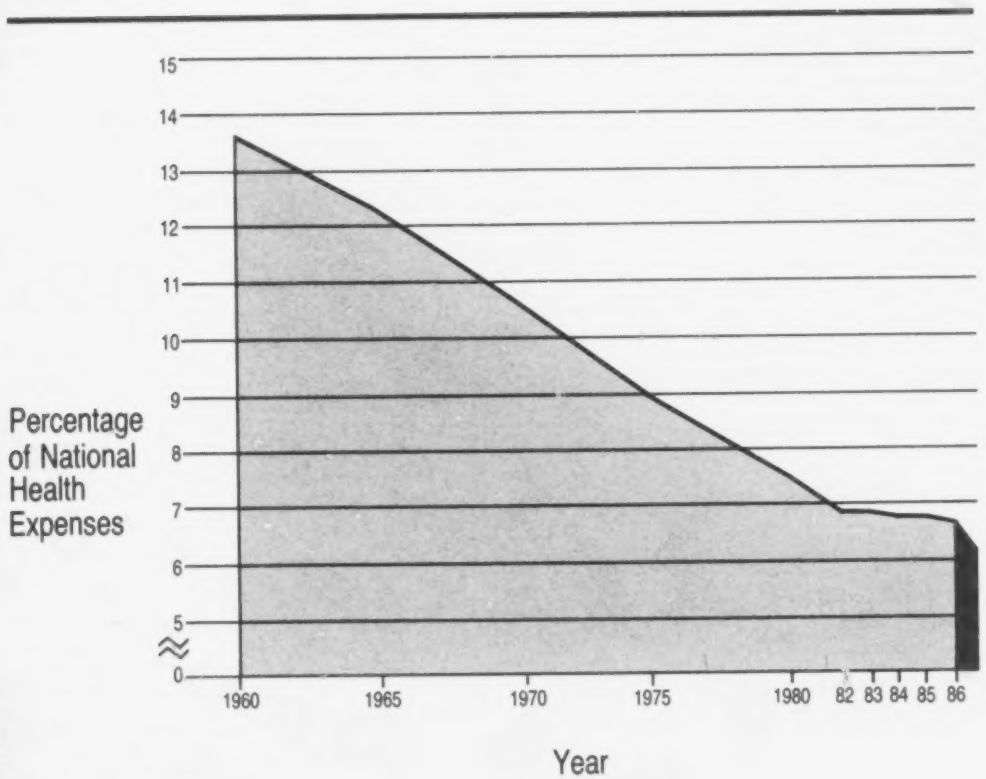


Source: Health Care Financing Administration.

Of every dollar spent on health care, less than seven cents is spent on drugs and sundries. That figure has declined steadily—down from 13.6 cents in 1960—despite the fact that drugs have displaced other more expensive forms of therapy.

Drugs As Percent Of National Health Expenditures On The Decline

Drugs As A Percentage of National Health Care Expenditures (Selected Calendar Years)

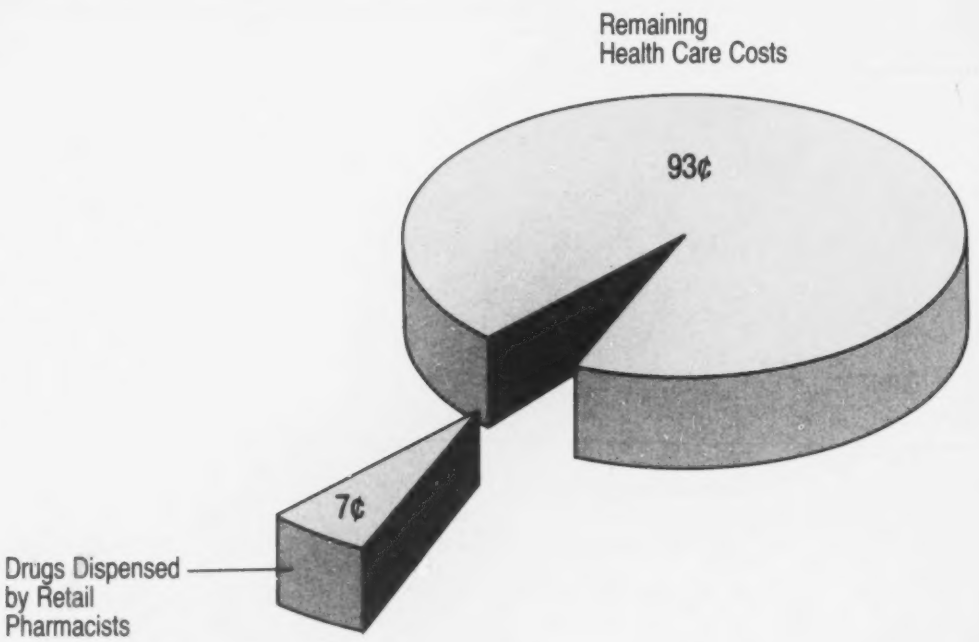


Source: Health Care Financing Administration.

Percent of Medicaid Expenditures For Drugs

In 1986, less than seven cents of every Medicaid dollar was spent on prescription drugs dispensed by retail pharmacists.

The Medicaid Dollar



Source: Health Care Financing Administration.

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CHAPTER I

THE PHARMACEUTICAL INDUSTRY IN THE U.S.

BACKGROUND ON THE INDUSTRY

Although U.S. pharmaceutical manufacturing dates back to the mid-nineteenth century, it began to emerge as a major industry about 40 years ago. Prior to the 1930s there were many small firms, but only a few conducted research. Most pharmaceutical preparations were compounded by pharmacists in their shops and dispensed directly to consumers.

Introduction of the first sulfa drug in 1935 stimulated interest in pharmaceutical research and set the stage for the successful development of penicillin, the most significant of many pharmaceuticals developed during World War II. Sulfa drugs and antibiotics saved the lives of countless Americans and allies during that period. The 15 years between 1938 and 1953 have come to be known as "The Age of Antibiotics" because a number of useful new anti-infectives were discovered. Leadership in the industry, in total sales as well as in new drug discoveries, shifted from Europe to the U.S. during World War II. American firms substantially increased their research and development efforts.

This strong commitment to drug research and development is demonstrated by continued U.S. leadership in the introduction of new chemical entities during the past 40 years. A detailed discussion of these new product introductions is presented in Chapter II.

Numerous laws govern the production, distribution, and marketing of prescription drugs on both the state and federal levels. Federal regulation began with the 1906 Pure Food and Drugs Act. This act was designed to protect consumers by requiring, in part, that the ingredients of a medicine be truthfully stated on the package label. This law was strengthened considerably in 1938 with the passage of the Food, Drug and Cosmetic Act, under which drug manufacturers were required to demonstrate that a drug was safe for the use stipulated on the label. Federal control over prescription drugs was broadened further by the 1962 Amendments to the Food, Drug and Cosmetic Act which required manufacturers to show that a new drug is effective for its intended uses.

INDUSTRY OVERVIEW

Marketing research data for 1986 indicate that approximately 680 corporations and companies in the U.S. are engaged in the manufacture and sale of ethical and proprietary pharmaceuticals.[1] The U.S. Department of Commerce estimated that the value of shipments of pharmaceutical products by all manufacturers was $25.3 billion in 1986. PMA member firms traditionally account for more than 90 percent of the industry's U.S. sales of human dosage form drugs.

Many prescription drug firms produce other health-related products. In addition to prescription and over-the-counter drugs, many large firms also make veterinary products and agricultural chemicals. A large number of companies also manufacture medical equipment, medical devices, diagnostic products, and hospital supplies. Some firms are important suppliers of chemicals used in other industries.

Drug manufacturing facilities are concentrated largely in New Jersey, New York, Pennsylvania, Indiana, Illinois, Michigan, Missouri, Ohio, California, and Puerto Rico. Through networks of distribution centers and wholesale distributors, pharmaceutical products are available to patients in more than 6,800 hospitals and 68,000 pharmacies.

SALES AND SALES GROWTH

For the period 1965-1987, total worldwide annual sales of PMA member firms grew by over 900 percent, from $4.1 billion to $41.2 billion (Table 1-1). Until recently, the major source of this growth was increased foreign sales. Annual domestic sales increased 700 percent, but foreign sales increased by more than 1,000 percent. In 1980, foreign sales represented 47 percent of total worldwide sales, compared to 27 percent in 1965. However, this percentage declined to 35 percent by 1986.

SALES BY PRODUCT CLASS

As sales have grown over the years, the percentage of total sales has changed for various classes of products. In 1986, sales in the U.S. of drugs acting on the central nervous system led all other categories. In addition, the relative share for cardiovascular drugs more than doubled from 1972 to 1986 (Table 1-2).

---

[1] Based on data from IMS, America Ltd.

TABLE 1-1

U.S. AND FOREIGN PHARMACEUTICAL SALES
PMA MEMBER FIRMS
1965-1986
($ millions)

Year	Domestic Sales Human	Domestic Sales Veterinary	Domestic Sales Total	Foreign Sales (including Exports) Human	Foreign Sales (including Exports) Veterinary	Foreign Sales (including Exports) Total	Total Domestic and Foreign
1986	$23,173.6	$933.2	$24,106.8	$12,218.2	$812.3	$13,030.5	$37,137.3
1985	20,265.0	888.5	21,153.5	10,129.6	742.7	10,872.3	32,025.8
1984	18,520.5	882.6	19,403.1	9,696.7	754.2	10,450.9	29,854.0
1983	16,218.2	876.8	17,095.0	9,645.4	765.8	10,411.2	27,506.2
1982	14,156.5	830.4	14,986.9	9,902.1	765.3	10,667.4	25,654.3
1981	12,100.4	761.6	12,872.0	9,895.2	763.1	10,658.3	23,530.3
1980	11,299.8	697.8	11,997.6	9,758.2	757.2	10,515.4	22,513.0
1979	9,558.8	644.2	10,203.0	7,916.2	648.6	8,564.8	18,767.8
1978	8,678.6	506.8	9,185.4	6,566.5	524.5	7,091.0	16,276.4
1977	7,907.1	428.6	8,335.7	5,403.8	406.7	5,810.5	14,146.2
1976	7,314.7	411.5	7,726.2	4,908.2	385.5	5,293.7	13,019.9
1975	6,602.8	301.0	6,903.8	4,467.6	328.7	4,796.3	11,700.1
1974	5,846.5	280.2	6,126.7	3,683.6	256.6	3,940.2	10,066.9
1973	5,258.6	269.1	5,527.7	3,078.5	199.5	3,278.0	8,805.7
1972	4,815.2	238.8	5,054.0	2,602.9	203.4	2,806.3	7,860.3
1971	4,510.4	199.0	4,709.4	2,212.7	175.2	2,387.9	7,097.3
1970	4,185.3	256.5	4,441.8	1,981.2	170.6	2,151.8	6,593.6
1969	3,894.8	216.4	4,111.2	1,702.3	154.5	1,856.8	5,968.0
1968	3,588.8	204.9	3,793.7	1,493.9	156.8	1,650.7	5,444.4
1967	3,199.1	211.8	3,410.9	1,350.8	147.2	1,498.0	4,908.9
1966	2,996.8	206.6	3,203.4	1,161.7	113.9	1,275.6	4,479.0
1965	2,773.1	180.7	2,953.8	998.5	99.2	1,097.7	4,051.5

Source: PMA Annual Survey.

Foreign sales of U.S. companies by product class, show different rankings than domestic sales with anti-infectives leading in sales in 1986 (Table 1-3).

TABLE 1-2

MANUFACTURERS' DOMESTIC SALES OF ETHICAL DRUGS FOR HUMAN USE
BY PRODUCT CLASS
1972*, 1982, 1983, 1985 and 1986

	Relative Share of Sales				
	1972	1982	1983	1985	1986
Central Nervous System	26.0%	25.2%	26.2%	26.4%	24.7%
Anti-Infectives	12.8	17.0	17.4	16.9	16.9
Gastrointestinal & Genitourinary	10.7	8.9	9.1	9.9	11.2
Neoplasms and Endocrine	12.0	13.5	13.3	12.5	13.0
Vitamins and Nutrients	7.6	8.3	5.6	4.2	3.8
Cardiovasculars	8.4	17.0	17.0	19.6	19.6
Respiratory System	6.6	5.2	5.9	5.7	6.3
Dermatologicals	3.3	2.8	2.6	2.4	2.3
Other	12.6	2.1	2.9	2.4	2.2
TOTALS	100.0%	100.0%	100.0%	100.0%	100.0%

* 1972 was the first year that data were reported consistently by product class.
Source: PMA Annual Survey.

TABLE 1-3

FOREIGN SALES OF ETHICAL DRUGS FOR HUMAN USE
BY PRODUCT CLASS AND DOSAGE FORM
1982, 1983 and 1986

	Relative Share of Sales		
	1982	1983	1986
Anti-Infectives	22.3%	21.3%	20.7%
Central Nervous System	16.2	15.4	15.5
Neoplasms and Endocrine	13.5	13.2	12.4
Gastrointestinal and Genitourinary	11.8	11.0	9.7
Respiratory System	9.0	9.6	7.7
Cardiovasculars	8.9	9.0	18.7
Vitamins and Nutrients	5.8	5.2	5.0
Dermatologicals	3.5	3.3	2.7
Biologicals	3.0	2.4	3.0
Diagnostic Agents	1.5	1.1	1.3
Other Pharmaceutical Preparations	4.5	8.5	3.3
TOTAL	100.0%	100.0%	100.0%

Source: PMA Annual Survey.

DISTRIBUTION OF SALES BY CUSTOMER TYPE

Table 1-4 shows the distribution, by class of customer, of human use, dosage form ethical pharmaceutical sales in the U.S. These sales are direct sales by the manufacturer. Retail pharmacies and hospitals, the usual sources of prescription drugs for patients, buy pharmaceuticals from wholesalers as well as directly from the manufacturer. However, manufacturers have shifted sales in recent years toward wholesalers and away from retailers.

TABLE 1-4

PERCENTAGE DISTRIBUTION OF U.S. ETHICAL PHARMACEUTICAL SALES
BY CLASS OF CUSTOMER
SELECTED YEARS 1972-1986

Class of Customer	1972	1974	1976	1978	1980	1982	1985	1986
Wholesalers	45.6%	45.2%	48.5%	51.4%	57.3%	59.6%	67.3%	68.3%
Retailers	29.4	28.1	26.4	22.8	20.8	18.0	16.0	15.5
Private Hospitals	14.6	15.6	14.8	16.0	12.7	13.7	8.8	8.0
State & Local Government Hospitals	4.7	4.8	4.5	4.2	4.1	3.8	2.5	2.3
Federal Hospitals	2.6	2.6	2.5	2.4	2.5	2.5	2.1	2.4
Other Federal Government	1.1	1.2	1.3	1.4	1.2	1.1	1.6	1.5
Practitioners	1.6	1.5	1.2	1.2	1.0	.8	.7	1.0
Manufacturers, Repackagers, and Other Direct Sales	.4	1.0	.8	.6	.4	.5	1.0	1.0
TOTAL	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Source: PMA Annual Survey (various years).

RETAIL SALES

Retail sales measure the value of drug products dispensed to the customer primarily through independent and chain retail pharmacies. The amount of money spent on prescription drugs is relatively small compared to the expenditures for other segments of health care. Sales of drugs and medical sundries in retail pharmacies accounted for only 6.7 percent of total national health expenditures in 1986. Retail pharmacy prescriptions alone accounted for about 3.9 percent of the national health dollar.

Table 1-5 shows retail prescription drug sales of $23.6 billion in 1987, an increase of 196 percent over 1976. The value of retail sales includes the cost of a product to the pharmacy as well as the retail mark-up or charge for professional dispensing services.

TABLE 1-5

U.S. RETAIL PRESCRIPTION DRUG SALES[2]
SELECTED YEARS
1976-1987

($ millions)

Year	Value of Sales
1987	$23,564.9
1986	21,248.8
1985	19,752.6
1984	17,884.4
1983	16,551.3
1982	15,129.0
1981	11,929.8
1980	10,400.5
1978	8,760.2
1976	7,965.1

Source: American Druggist, May 1979, May 1982, 1983, 1984, 1985, May 1986, May 1987, and May 1988.

Retail sales figures are determined in part by the volume of prescriptions dispensed. Total prescriptions increased by 11.8 percent from 1977 to 1987 to 1.58 billion prescriptions (Table 1-6). However, the apparent small increase in retail prescriptions does not reflect the fact that the average prescription size is about 14 percent larger than it was in 1976.[3]

[2] 1987 American Druggist data is not comparable with previously published data because of methodological changes in the American Druggist survey. Figures for 1976-1986 were estimated by PMA to provide a data series consistent with the 1987 estimate.

[3] While significant changes have been made in the IMS, National Prescription Audit database, particularly in 1981 and 1983, it is unlikely that these changes had any effect on the trends shown in Table 1-6.

TABLE 1-6

U.S. PRESCRIPTION VOLUME
1977-1987

Year	New Rx's	Percent Change	Refills	Percent Change	Total Rx's	Percent Change
1977	726,675,000	-1.9	685,982,000	-4.7	1,412,657,000	-3.3
1978	743,552,000	2.3	653,336,000	-4.8	1,396,888,000	-1.1
1979	732,535,000	-1.5	633,323,000	-3.1	1,365,858,000	-2.2
1980	750,289,000	2.4	644,019,000	1.7	1,394,308,000	2.1
1981	737,797,000	-1.7	681,772,000	5.9	1,419,569,000	1.8
1982	768,189,000	4.1	729,994,000	7.1	1,498,183,000	5.5
1983	742,399,000	-3.4	765,735,000	4.9	1,508,134,000	.7
1984	750,118,000	1.0	781,630,000	2.1	1,531,748,000	1.6
1985	755,468,000	0.7	792,944,000	1.4	1,548,412,000	1.1
1986	784,483,000	3.8	773,028,000	-2.5	1,557,511,000	0.6
1987	817,081,000	4.2	762,495,000	-1.4	1,579,576,000	1.4

Source: IMS, National Prescription Audit, Various Years.

INTERNATIONAL OPERATIONS

The U.S. pharmaceutical industry is the largest of any nation. Although organized primarily to satisfy the large domestic market, American producers are exceptionally active in foreign trade and investment, and contribute substantially to the U.S. balance of payments.

The most comprehensive measure of the industry's contribution to the balance of payments emerges from data compiled by the International Trade Administration, U.S. Department of Commerce. These data include finished dosage form preparations, biologicals and medicinal chemicals which include drugs in bulk such as sulfonamide and acetylsalicylic acid, enzymes, certain inorganic medicinal chemicals and prepared culture media.

Since 1982, the balance of trade in pharmaceuticals has declined almost 68 percent, but remains positive at $394 million in 1987 (Table 1-7). The high value of the dollar in the early 1980s was a significant factor in the declining trade balance.

According to United Nation's statistics for 1984 (Table 1-8), the United States is the world's largest exporter and importer of pharmaceutical products. U.S. pharmaceutical products are sold in nearly every country of the free world. Japan is by far the leading recipient of U.S. pharmaceutical exports, receiving over 20 percent of the total. Almost one-half of U.S. exports are sent to Europe, and over 20 percent go to developing countries (Table 1-9).

TABLE 1-7

FOREIGN TRADE OF THE UNITED STATES IN
MEDICINALS AND PHARMACEUTICAL PREPARATIONS
1979-1987
($ Millions, f.a.s. values)

Year	Total Exports	Total Imports	Net Exports
1979	1634.1	874.6	759.5
1980	1966.1 (+20.3%)	930.7 (+ 6.4%)	1035.4 (+36.3%)
1981	2199.8 (+11.6%)	1048.7 (+13.0%)	1151.1 (+11.2%)
1982	2298.4 (+ 4.9%)	1051.3 (+ 4.0%)	1247.1 (+ 8.3%)
1983	2533.2 (8.8%)	1312.4 (+22.2%)	1220.8 (- 2.1%)
1984	2637.3 (4.1%)	1665.1 (+26.9%)	972.2 (-20.4%)
1985	2671.3 (1.3%)	1895.8 (13.9%)	775.5 (-20.2%)
1986	3086.5 (15.5%)	2322.2 (22.5%)	764.2 (- 1.5%)
1987	3216.3 (4.2%)	2822.0 (21.5%)	394.3 (-48.4%)

(Percentages in the table above indicate changes from the preceding year.)

Source: International Trade Administration, U.S. Department of Commerce.

TABLE 1-8

WORLD TRADE IN MEDICINAL AND PHARMACEUTICAL PRODUCTS
1984
($ Thousands)

Countries	Exports	Imports	Balance of Trade
Leading Net Exporters			
United States	$2,759,028	$1,500,068	$1,258,960
Switzerland	1,508,181	431,081	1,077,100
Germany (F.R.)	2,160,007	1,224,511	935,496
United Kingdom	1,638,998	727,760	911,238
France	1,396,175	716,140	680,035
Denmark	397,818	213,269	184,549
Belgium	637,474	535,770	101,704
Netherlands	584,933	502,456	82,477
Yugoslavia	163,433	89,611	73,822
Sweden	373,887	307,332	66,555
Ireland	199,581	166,103	33,478
Singapore	121,990	104,345	17,645
Leading Net Importers			
Greece	$ 37,045	$122,655	$ -85,610
Portugal	38,328	124,826	-86,498
Korea Republic	32,443	119,126	-86,683
Indonesia	15,547	104,337	-88,790
Argentina	30,262	123,344	-93,082
Norway	41,606	134,245	-92,639
Mexico	58,187	156,447	-98,260
Thailand	10,413	114,102	-103,689
Austria	203,649	311,089	-107,440
Australia	93,230	219,292	-126,062
Egypt	10,460	151,913	-141,453
African Customs Union	13,992	182,276	-168,284
Canada	166,157	478,895	-312,738
Japan	355,476	1,258,490	-903,014

Source: 1984 International Trade Statistics Yearbook, U.N.

TABLE 1-9

FOREIGN TRADE OF THE UNITED STATES IN
MEDICINALS AND PHARMACEUTICAL PREPARATIONS BY WORLD AREAS
1981-1987
(Thousands of dollars, f.a.s. values)

Area	1981	1982	1983	1984	1985	1986	1987
Canada:							
Exports	$150,031	$166,099	$183,956	$185,230	$195,295	$205,330	$239,964
Imports	22,410	26,701	28,120	26,934	29,742	32,953	41,988
Net U.S. Exports	$127,621	$139,398	$155,836	$158,296	$165,553	$172,377	$197,976
Latin American Republics:							
Exports	$284,926	$271,512	$256,454	$280,425	$270,566	$327,334	$329,235
Imports	34,268	32,491	27,955	27,248	32,471	40,805	44,135
Net U.S. Exports	$250,658	$239,021	$228,499	$253,177	$238,095	$286,529	$285,100
Other Western Hemisphere:							
Exports	$ 29,009	$ 33,710	$ 35,014	$ 44,223	$ 41,686	$ 47,388	$ 29,681
Imports	42,115	48,526	64,404	67,620	83,532	142,327	122,661
Net U.S. Exports	$(13,106)	$(14,816)	$(29,390)	$(23,397)	$(41,846)	$(94,939)	$(92,980)
United Kingdom							
Exports	$108,238	$117,445	$172,584	$167,537	$157,659	$191,905	$164,993
Imports	145,666	157,768	269,293	366,640	366,196	436,211	494,487
Net U.S. Exports	$(444,428)	$40,323)	$(66,709)	$(199,103)	$(208,537)	$(244,306)	$(329,494)
E.E.C. Countries (inc. U.K.):							
Exports	$773,452	$790,826	$923,755	$929,074	$966,466	$1,158,768	$1,198,768
Imports	602,107	587,430	765,382	1,050,760	1,053,001	1,177,309	1,496,081
Net U.S. Exports	$171,345	$203,396	$158,373	$(121,686)	$(86,535)	$(18,541)	$ (297,313)
OECD Countries of Europe:							
Exports	$952,122	$976,019	$1,155,205	$1,075,675	$1,202,085	$1,487,962	$1,512,257
Imports	722,821	717,382	910,041	1,241,166	1,359,862	1,541,424	1,936,469
Net U.S. Exports	$229,301	$258,637	$ 245,164	$ (165,491)	$ (157,777)	$ (53,462)	$ (424,212)
Japan:							
Exports	$442,960	$504,106	$537,023	$563,339	$581,081	$637,009	$688,733
Imports	159,465	148,505	188,133	189,728	201,318	321,220	401,490
Net U.S. Exports	$283,495	$355,601	$348,890	$373,611	$379,763	$315,789	$287,243

TABLE 1-9
(Continued)

FOREIGN TRADE OF THE UNITED STATES IN
MEDICINALS AND PHARMACEUTICAL PREPARATIONS BY WORLD AREAS
1981-1987

(Thousands of dollars, f.a.s. values)

Area	1981	1982	1983	1984	1985	1986	1987
Other Asia:*							
Exports	$228,173	$246,235	$247,356	$271,566	$254,431	$246,546	$287,344
Imports	25,717	28,566	33,838	49,446	105,138	155,405	181,978
Net U.S. Exports	$202,456	$217,669	$213,518	$222,120	$149,293	$ 91,141	$105,366
Australia & Oceania:							
Exports	$ 50,264	$ 48,210	$ 58,985	$ 65,436	$ 66,448	$ 65,745	$ 70,674
Imports	3,796	8,042	11,801	12,262	17,583	13,400	12,533
Net U.S. Exports	$ 46,468	$ 40,168	$ 47,184	$ 53,174	$ 48,865	$ 52,345	$ 58,141
Africa:							
Exports	$ 42,115	$ 39,261	$ 45,570	$ 52,396	$ 42,686	$ 52,397	$ 45,649
Imports	1,011	1,211	1,357	1,917	3,175	3,199	3,409
Net U.S. Exports	$ 41,104	$ 38,050	$ 44,213	$ 50,479	$ 39,511	$ 49,198	$ 42,240
Principal Developing Areas:**							
Exports	$584,223	$590,718	$584,394	$648,610	$620,229	$682,933	$691,909
Imports	103,111	110,794	127,554	146,231	275,044	401,790	352,183
Net U.S. Exports	$481,112	$479,924	$456,840	$502,379	$345,185	$281,143	$339,726
World Total:***							
Exports	$2,199,811	$2,298,399	$2,533,200	$2,637,329	$2,671,332	$3,086,547	$3,216,340
Imports	1,048,729	1,051,257	1,312,394	1,665,085	1,895,831	2,322,288	2,822,004
Net U.S. Exports	$1,151,082	$1,247,142	$1,220,806	$ 972,244	$ 775,501	$ 764,259	$ 394,336

*Excludes Japan and Communist Asia.
**Based on combined figures for Latin America, other Western Hemisphere, Asia other than Japan and Communist areas, and Africa.
***Totals include Communist areas not shown separately above.

Source: International Trade Administration, U.S. Department of Commerce.

In large part, U.S. exports of pharmaceutical products consist of ingredients and intermediate products sent abroad to be processed and packaged. This practice reflects practical considerations such as convenience in satisfying a market, the need to label medicines in a foreign language and the desire to meet the preferences of local doctors and patients for certain dosage forms. The passage of the Omnibus Health Act in 1986 opened new exporting opportunities for pharmaceutical firms. Under the new law, firms can now export drugs that have not been approved by the U.S. Food and Drug Administration to a select list of countries that have approved the drugs. These drugs must be under clinical study here in the U.S. to be eligible for exporting.

In other cases, manufacturing abroad is encouraged by tariff or non-tariff barriers to imports, national laws, or other policies of a foreign country that make it difficult or impossible to market a product unless it is largely produced within its boundaries. In most instances, production in foreign countries has been a means of achieving sales that otherwise would not have been possible. Through foreign subsidiaries and affiliates, many U.S. companies increase their shipments of bulk materials and ingredients as well as supplies and equipment. This helps to sustain or expand U.S. domestic employment.

The production and sales of major companies through their networks of affiliates in other countries have contributed significantly to the industry's international importance. U.S. sales abroad, directly and through foreign branches and subsidiaries, exceeded $12 billion in 1986. These operations abroad have made important contributions to the economies of the countries in which the subsidiary operations are located. Foreign subsidiaries of U.S. firms establish local facilities that provide training and employment for local workers, add to tax revenues, contribute to the balance of payments of the host country, support local corollary industries, and reinvest earnings in the host country. In turn, various Swiss, West German, French and British firms have long owned and operated plants in the U.S.

Many PMA companies have subsidiaries or jointly-owned affiliates in other countries, and many other member companies engage in international operations through licensing and exporting. Sales achieved through manufacturing abroad greatly exceed direct exports from the U.S. (Table 1-10). Combined sales abroad in 1986 were more than double the total ten years earlier.

Although most pharmaceutical sales abroad by U.S. companies are made to other advanced countries, U.S. companies also have significant pharmaceutical activities in developing countries. Many U.S. firms enjoy long-established relationships with Latin America and several countries in Asia and Africa. In fact, the U.S. pharmaceutical industry has invested heavily in

TABLE 1-10

FOREIGN SALES OF ETHICAL PHARMACEUTICALS
BY U.S.-OWNED PMA MEMBER FIRMS
1965-1986
($ Millions)

Year	Total Foreign Sales	Sales Abroad	Exports
1965	$ 1,097.7	$ 917.7	$ 180.0
1966	1,275.6	1,074.6	201.0
1967	1,498.0	1,281.5	216.5
1968	1,650.7	1,424.8	225.9
1969	1,856.8	1,559.5	297.3
1970	2,151.8	1,807.7	344.1
1971	2,387.9	2,005.5	382.4
1972	2,806.3	2,428.4	377.9
1973	3,278.0	2,712.4	565.6
1974	3,940.2	3,206.2	734.0
1975	4,796.3	4,042.6	753.7
1976	5,293.7	4,398.9	894.8
1977	5,810.5	4,862.9	947.6
1978	7,091.0	6,026.3	1,064.7
1979	8,564.8	7,410.0	1,154.8
1980	10,515.4	9,296.1	1,219.3
1981	10,658.4	9,264.5	1,393.9
1982	10,667.4	9,221.1	1,446.3
1983	10,411.2	9,075.5	1,335.7
1984	10,450.9	9,110.1	1,340.8
1985	10,872.3	9,315.4	1,556.9
1986	13,030.5	10,986.3	2,044.2

"Exports" includes shipments to subsidiaries abroad as well as exports to nonaffiliated firms. These data are based on ethical pharmaceutical sales provided by member companies and are not directly comparable with Commerce Department or United Nations trade data.

"Sales Abroad" refers to sales in a foreign area by subsidiaries or other corporate operations, adjusted to eliminate double counting of intrafirm transactions. Also excluded are sales outside the U.S. by foreign-owned firms which have subsidiaries in the U.S.

Source: PMA Annual Survey, various years.

developing countries, employing thousands of local workers and helping build technological expertise.

Earning rates vary in foreign countries because many foreign governments impose price controls, and because of different risks and competitive factors. In addition to direct earnings from sales, patent royalties, fees received for management and engineering services, and other remittances from abroad help the industry improve the U.S. balance of payments.

CONCENTRATION

The Bureau of the Census compiles statistics on concentration ratios for over 400 American industries in the quinquennial Census of Manufacturers. These statistics include the share of total sales held by the four largest, eight largest and 20 largest firms in each industry.

Some industries, such as automobile or primary aluminum, are highly concentrated in that only a few companies account for a major share of industry sales. Other industries, such as concrete or commercial printing, have very low rates of concentration. The four-firm concentration ratio for the pharmaceutical industry ranks in the bottom 40 percent among the total of approximately 450 U.S. industries examined by the Bureau of Census (Table 1-11).

Using marketing research data, it is also possible to look at concentration ratios in terms of market share of new and refill prescription dollars. Table 1-12 includes data for 1979 through 1987. These data indicate that concentration in the industry has been relatively stable, declining only slightly in recent years.

TABLE 1-11

CONCENTRATION RATIOS FOR FIRMS MANUFACTURING PHARMACEUTICAL PREPARATIONS (SIC 2834)
Selected Years, 1958-1982

		Percent of value of shipments accounted for by:		
Year	Number of Establishments	4 Largest Companies	8 Largest Companies	20 Largest Companies
1958	1,114	25%	43%	71%
1963	1,011	22	37	71
1967	875	24	40	70
1972	756	25	43	73
1977	756	25	41	70
1982	683	26	41	67

Source: 1982 Census of Manufacturers, Pub.MC77-Sr-9, Subject Series, Bureau of Census, U.S. Department of Commerce, 1986.

TABLE 1-12

COMPETITION FOR NEW U.S. PRESCRIPTIONS
MEASURED IN TOTAL PRESCRIPTION DOLLARS

1979-1987

	Percentage of New and Refill Prescription Dollars [a,b,c,d]								
Company Group	1979	1980	1981	1982	1983	1984	1985	1986	1987
Leading Company	10.1%	9.8%	9.2%	8.4%	8.3%	8.4%	7.5%	6.8%	7.2%
4 Largest	32.3	31.6	30.5	29.5	29.6	29.2	27.1	25.0	23.6
8 Largest	50.2	50.1	49.8	48.9	48.4	47.7	44.7	43.3	41.4
20 Largest	81.9	81.8	81.9	79.4	78.4	77.0	74.1	72.6	71.9
50 Largest	98.8	98.8	98.7	96.7	96.1	96.2	94.3	95.7	95.4
All Companies	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

a "Unspecified" prescriptions not included in calculations for the years 1978-1981. The Unspecifieds accounted for 6.4 percent to 6.8 percent of total Rx dollars between 1978 and 1981.

b Pharmacy cost level.

c Data for 1982-1987 are for prescriptions as they were dispensed, not prescribed as was the case for earlier years.

d Sales of subsidiaries were combined with parent corporation sales in making calculations.

Source: National Prescription Audit, IMS America, Ltd.

One additional measure of industry concentration--the Herfindahl-Hirschman Index (HHI)--has been used to examine the effects of proposed mergers. This measure has been advocated as the appropriate market power measure for antitrust purposes.[4]

Table 1-13 shows the HHI values[5] computed for 1978 through 1986, using the same data upon which the concentration ratios of Table 1-12 were based. In examining the impact of merger activity, the critical value of the HHI that would trigger concern about a particular merger is not well-established. However, a value of 1000 is generally viewed as being unlikely to be challenged. As Table 1-13 shows, the pharmaceutical industry HHI is less than half of this usually accepted value and in fact has declined by 23 percent since 1980.

TABLE 1-13

PHARMACEUTICAL INDUSTRY CONCENTRATION
HERFINDAHL-HIRSCHMAN INDEX VALUES
1978-1986

Year	Index Value
1978	440
1979	453
1980	446
1981	439
1982	414
1983	411
1984	394
1985	368
1986	342

Source: PMA calculations based on data from National Prescription Audit data, IMS, America.

EARNINGS

In a very real sense, earnings represent the end of the research-marketing-physician-pharmacist-consumer chain. Earnings also provide the capital necessary to finance a new cycle of research and so can be considered a beginning as well.

[4] Department of Justice Antitrust Division-Merger Guidelines, Federal Register, (June 1982), 28494-28502.

[5] The HHI is computed by squaring the market share for each firm, expressed in percent, and summing the result. This sum is then multiplied by 10,000 to express the HHI value in whole numbers.

By most measures, the pharmaceutical industry is profitable, with earnings traditionally above the average for all manufacturing industries. However, the concept of profitability is not sufficiently well-defined to rely on a single measure of profitability. No single measure conveys appropriate information to all economic agents interested in the performance of the industry. The results obtained using accounting data may differ from those obtained using capital market data.

Some commonly used accounting measures of profitability are: return on sales, return on stockholders' equity, return on capital employed, and return on assets. Return to investors[6] is an example of a capital market measure. To illustrate how relative profitability is sensitive to the measure of profitability chosen, consider the Fortune 500 Corporations for 1980-1987[7] and the following three measures of profitability.

(i) Return on Sales
(ii) Return on Stockholders' Equity
(iii) Return to Investors

Each firm in the Fortune 500 is classified into one of 26 industries including pharmaceuticals. The medians for the pharmaceutical industry and "all industries" for each of the three measures of profitability used in Fortune are given in Table 1-14.

The question of which measures of profitability are most appropriate for evaluating an industry remains a matter of personal judgment rather than logical derivation. However, policy discussions will often focus on measures that use readily available accounting data on sales, net income (earnings), and stockholders' equity. Earnings as a percent of sales both before and after taxes, are displayed in Table 1-16. Earnings as a percent of stockholders' equity are shown in Table 1-17.

Based on these measures of profitability, the pharmaceutical industry is a profitable industry. However, the industry also leads in terms of the percentage of its sales reinvested in R&D which involves considerable risks. The industry invested an estimated 15.1 percent of its sales in research and development in 1987.

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[6] Return to investors includes both stock price appreciation and dividend yield.

[7] There are 17-25 pharmaceutical firms included in each edition of Fortune 500.

TABLE 1-14

MEDIAN RETURN (%)
PHARMACEUTICAL/ALL INDUSTRIES

Year	Sales	Equity	Investors
1980	9.1/4.8	17.9/14.4	Not Available
1981	9.1/4.6	18.0/13.8	3.07/-.35
1982	9.9/3.6	16.9/10.9	32.82/21.22
1983	10.4/3.8	17.5/10.7	7.18/30.21
1984	10.0/4.5	18.1/13.6	7.78/.75
1985	10.4/3.9	15.6/11.6	11.47/24.13
1986	13.1/4.1	23.6/11.6	27.90/15.50
1987	13.2/4.6	22.7/13.2	11.7/6.8

Source: Fortune, various issues.

TABLE 1-15

RANK OF THE PHARMACEUTICAL INDUSTRY
(PROFITABILITY)
AMONG 26 INDUSTRIES

Year	Sales	Equity	Investors
1980	2	4	Not Available
1981	2	3	12
1982	1	1	11
1983	1	2	21
1984	1	3	6
1985	1	6	20
1986	1	1	6
1987	9	8	7

Source: Fortune, various issues.

The risks involved in the research process are highlighted by the uncertainty about whether large investments in R&D will yield commercially successful products. Risk factors are not adequately taken into account in profitability comparisons based on traditional earnings measures. The U.S. Department of Commerce

TABLE 1-16

COMPARATIVE EARNINGS STATISTICS
EARNINGS AS A PERCENT OF SALES
1970-1987[a]

	Before Taxes		After Taxes	
Year	Pharmaceutical Industry	All Manufacturing	Pharmaceutical Industry	All Manufacturing
1970	17.2%	6.8%	9.4%	4.0%
1971	17.0	7.1	9.5	4.2
1972	18.1	7.5	10.3	4.3
1973	17.8	8.0	10.2	4.7
1974	19.3	8.7	12.2	5.5
1975[b]	19.3	7.5	12.3	4.6
1976	19.0	8.7	12.2	5.4
1977[b]	19.2	8.7	12.1	5.3
1978	19.1	8.9	12.5	5.4
1979[b]	18.6	8.9	12.9	5.7
1980[b]	18.6	7.7	13.2	4.8
1981[b]	15.6	7.4	10.9	4.8
1982[b]	17.9	5.3	13.1	3.5
1983	19.3	6.3	13.4	4.0
1984	19.1	7.1	13.3	4.6
1985	14.6	5.9	9.8	3.8
1986	20.7	5.8	14.5	3.7
1987	15.8	7.3	10.5	4.9

[a] Ratios were calculated using fourth quarter reports.
[b] First quarter reports for the succeeding year were used to calculate these ratios.

Source: Quarterly Financial Report (for manufacturing, mining, and trade corporations), 1970--First Quarter 1982, U.S. Federal Trade Commission; Second Quarter, 1982-1987, U.S. Department of Commerce.

has noted that "in this respect, some economists have shown that profitability analysis in the pharmaceutical industry is misleading for several reasons. First, the accounting profits or rates of return of an individual project may be significantly higher during the early years of new drug sales. Second, there is a long time lag, five to ten and sometimes many more years, between the investment and the return on the investment.[7]"

TABLE 1-17

COMPARATIVE EARNINGS STATISTICS
EARNINGS AS A PERCENT OF STOCKHOLDERS' EQUITY
1970-1987[a]

	Before Taxes		After Taxes	
Year	Pharmaceutical Industry	All Manufacturing	Pharmaceutical Industry	All Manufacturing
1970	32.4%	15.7%	17.6%	9.3%
1971	31.2	16.5	17.9	9.7
1972	32.8	18.4	18.6	10.6
1973	33.1	21.8	19.0	12.8
1974	29.7	23.3	18.8	14.9
1975[b]	27.8	18.9	17.8	11.6
1976	28.2	22.7	18.1	14.0
1977[b]	28.9	23.2	18.2	14.2
1978	28.6	24.5	18.8	15.0
1979[b]	27.9	25.7	19.3	16.5
1980[b]	27.9	22.0	19.9	14.0
1981[b]	24.2	21.4	16.9	13.7
1982[b]	27.0	14.1	19.7	9.3
1983	29.2	16.4	20.3	10.6
1984	28.9	19.1	20.2	12.4
1985	22.5	15.8	15.2	10.1
1986	32.6	14.9	22.9	9.6
1987	26.5	19.0	17.4	12.7

[a] Ratios were calculated using fourth quarter reports.
[b] First quarter reports for the succeeding year were used to calculate these ratios.

Source: Quarterly Financial Report (for manufacturing, mining, and trade corporations), 1970--First Quarter 1982, U.S. Federal Trade Commission; Second Quarter, 1982-1987, U.S. Department of Commerce.

[7] A Competitive Assessment of the U.S. Pharmaceutical Industry, International Trade Administration, U.S. Department of Commerce, December, 1984.

EMPLOYMENT AND EARNINGS

In 1985, the U.S. pharmaceutical industry employed 312,700 persons worldwide. Employment abroad by U.S. firms represented 47.4 percent of the worldwide figure in 1985, but declined to 46.5 percent in 1986 (Table 1-18). Table 1-19 shows the distribution of pharmaceutical employees in the U.S.

TABLE 1-18

U.S. ETHICAL PHARMACEUTICAL INDUSTRY EMPLOYMENT

1985 AND 1986

	Number of Workers	
	1985	1986
United States	164,400	170,590
Foreign	148,300	148,500
TOTAL	312,700	319,090

Source: PMA Annual Survey, 1985-1986.

TABLE 1-19

ETHICAL PHARMACEUTICAL EMPLOYMENT IN THE U.S.

1985 AND 1986

	1985	1986
Production Workers	58,600	63,600
Marketing	44,600	46,300
Medical Research & Development	35,800	37,790
Administrative	18,100	16,800
Distribution & Other	7,300	6,100
TOTAL U.S. Employment	164,400	170,590

Source: PMA Annual Survey, 1985-1986.

PRODUCTIVITY

Employees in the pharmaceutical industry have increased productivity faster than employees engaged in other lines of business. From 1975 to 1986, pharmaceutical productivity increased 24 percent. For all non-farm businesses, the increase was 13.2 percent.

TABLE 1-20

INDEXES OF PRODUCTIVITY
U.S. PHARMACEUTICAL INDUSTRY AND U.S. PRIVATE NON-FARM BUSINESS
1971-1987

(1977 = 100)

Year	Index of Output (Production) Per Employee Hour	
	Pharmaceutical Industry	Non-Farm Business
1971	81.0	92.4
1972	86.8	94.8
1973	84.8	96.3
1974	90.3	94.2
1975	92.5	96.2
1976	98.4	98.3
1977	100.0	100.0
1978	98.5	100.8
1979	105.3	99.2
1980	106.0	98.9
1981	104.2	99.8
1982	107.0	99.6
1983	115.2	103.3
1984	114.3	105.1
1985	111.9	106.2
1986	114.8	107.8
1987	Not available	108.9

Source: Office of Publications, U.S. Bureau of Labor Statistics, U.S. Department of Labor, (various statistical series).

CHAPTER II

THE INDUSTRY'S COMMITMENT TO RESEARCH AND DEVELOPMENT

RESEARCH AND DEVELOPMENT EXPENDITURES

The pharmaceutical industry has invested over $36 billion in pharmaceutical research and development (R&D) since the early 1940s. This research commitment led to the discovery of more than 1,100 new chemical entities that have helped prevent disease, cure illness, prolong life and reduce the cost of being sick. Total worldwide R&D spending by PMA member companies was $4.1 billion in 1985 and $4.7 billion in 1986. Spending for 1987 is estimated at $5.4 billion. These figures include spending for both human-use and veterinary products.

Research by U.S. firms abroad accounted for $865 million in 1986--18.3 percent of the total amount. For 1987, U.S. R&D abroad was estimated at $954 million or 17.8 percent of total R&D spending (Figure 2-1). In 1970, research abroad represented only eight percent of total R&D spending by U.S. firms.

Companies finance almost all of their R&D, although they also conduct a very limited amount of research under contract with the federal government. Over the last 17 years, these government funded projects involved annual expenditures ranging as high as $14 million. In 1986, federally-financed R&D amounted to $4.1 million, or less than one percent of the industry total. The estimated total for federal funds in 1987 was $4.6 million.

R&D-TO-SALES RATIO

A key measure of the industry's continued commitment to research is the ratio of annual R&D expenditures to dollar volume of pharmaceutical sales. Expressed as a percentage, the ratio has been above ten percent each year since 1965 and since 1980 has increased by 29 percent from 11.7 percent to 15.1 percent (Table 2-1).

ALLOCATION OF RESEARCH FUNDS

Allocation to Product Innovation. In 1986, almost 84 percent of U.S. R&D expenditures were devoted to the quest for new scientific knowledge and the development of new therapies. Improvement of existing products represented the remaining 16 percent.

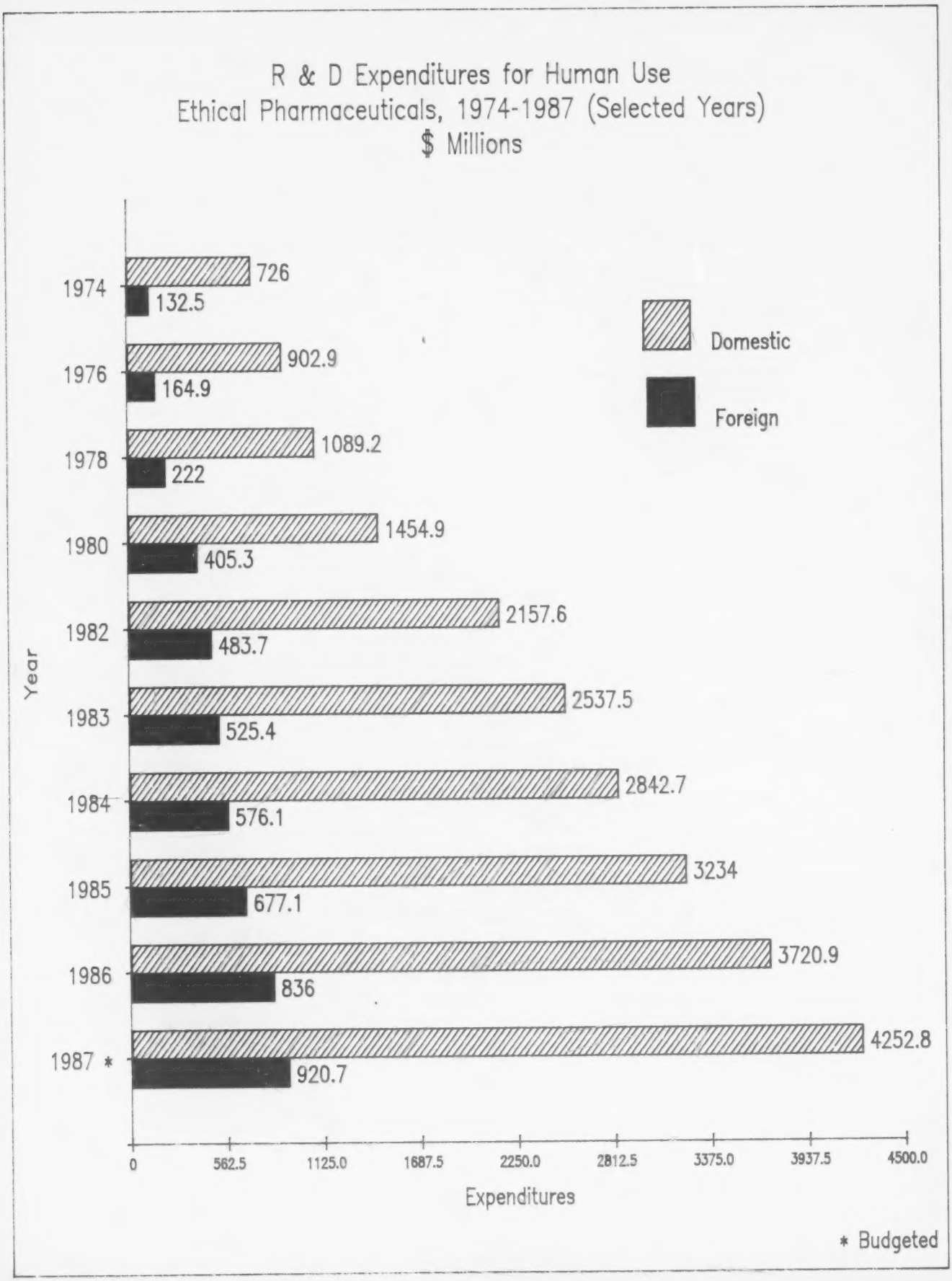

R & D Expenditures for Human Use
Ethical Pharmaceuticals, 1974-1987 (Selected Years)
$ Millions
Year
1974
726
132.5
1976
902.9
164.9
1978
1089.2
222
1980
1454.9
405.3
1982
2157.6
483.7
1983
2537.5
525.4
1984
2842.7
576.1
1985
3234
677.1
1986
3720.9
836
1987 *
4252.8
920.7
Domestic
Foreign
0
562.5
1125.0
1687.5
2250.0
2812.5
3375.0
3937.5
4500.0
Expenditures
* Budgeted

Table 2-1
U.S. PHARMACEUTICAL R&D EXPENDITURES
AS A PERCENTAGE OF U.S. PHARMACEUTICAL SALES*
1965-1987

YEAR	PERCENT	YEAR	PERCENT
1965	10.2%	1976	11.3%
1966	10.8	1977	11.3
1967	11.3	1978	11.1
1968	10.9	1979	11.4
1969	11.1	1980	11.7
1970	11.6	1981	13.1
1971	12.1	1982	13.8
1972	11.8	1983	14.4
1973	11.4	1984	14.4
1974	11.3	1985	14.8
1975	11.6	1986	14.8
		1987	15.1

* Includes U.S. sales plus exports.

Source: PMA Annual Survey Report.

ALLOCATION BY PRODUCT CLASS

Survey data for 1986 show that the pharmaceutical industry targets its research and development on major health problems. For example, about 72 percent of U.S. R&D expenditures were directed to finding new drugs to treat cardiovascular diseases, infections, neoplasms and central nervous system problems. Expenditures were highest for drugs acting on the cardiovascular system and neoplasms.

Table 2-2 shows the allocation of funding among all product classes, with each class representing drugs useful against a common set of health problems, symptoms, or diseases.

FOREIGN RESEARCH AND DEVELOPMENT

Since 1967, the share of U.S. company-funded R&D work carried out overseas by U.S. firms more than doubled. One reason for this is that costs are lower in some other countries. Another factor is the lengthy approval process for new drugs in the U.S. All major countries have strict rules for approving new pharmaceutical products, but few--if any--countries take as long as the U.S.

Table 2-3 shows the recent trend in foreign research expenditures by domestic firms. Figure 2-2 shows graphically the historical shift of research activity from the U.S. to foreign countries.

TABLE 2-2
U.S. PHARMACEUTICAL R&D EXPENDITURES BY PRODUCT CLASS
1985 - 1986

Ranking 1986	Ranking 1985	Product Class	Percentage Share of R&D Dollar 1985	1986
1	1	Cardiovasculars	25.8%	25.8%
2	2	Neoplasms, Endocrine System & Metabolic Diseases	18.1	18.1
4	3	Anti-infectives	14.9	13.9
3	4	Central Nervous System & Sense Organs	12.9	14.2
6	5	Gastrointestinal & Genitourinary System	5.8	5.7
5	6	Respiratory	5.7	6.2
7	7	Biologicals	2.6	2.3
8	8	Dermatologicals	1.7	2.0
9	9	Vitamins	1.1	.5
10	10	Diagnostic (in vivo)	.7	.5
		Other Human Use Drugs	6.6	7.4
		Veterinary Preparations	3.7	3.1
		Veterinary Biologicals	.4	.3
			100.0%	100.0%

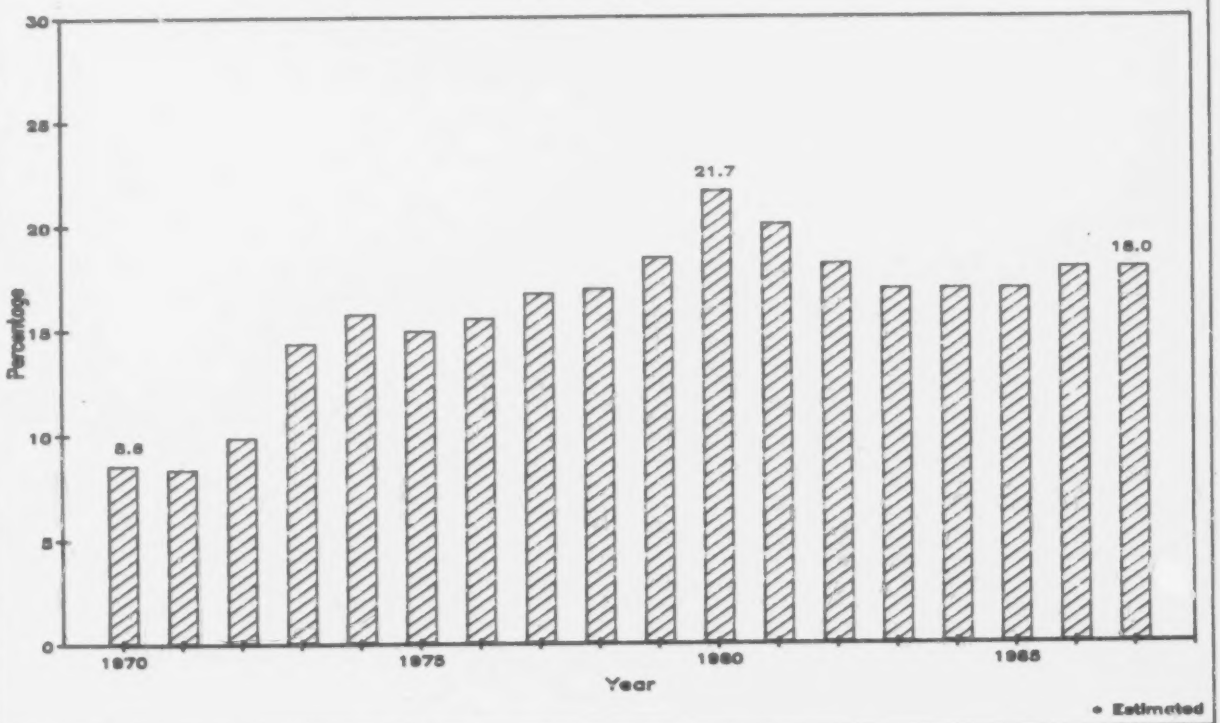
Source: PMA Annual Survey Report.

TABLE 2-3
R&D EXPENDITURES OF U.S. COMPANIES IN FOREIGN COUNTRIES
1984-1987
($ Millions)

	1984	1985	1986	1987*
Spent within firms:				
Human Use	$480.7	$564.7	$700.7	$760.8
Veterinary Use	14.3	15.4	21.0	23.7
Spent outside firms:				
Human Use	95.4	112.4	135.3	159.9
Veterinary Use	6.0	6.4	8.1	9.2
Total Expenditures:				
Human Use	576.1	677.1	836.0	920.7
Veterinary Use	20.3	21.8	29.1	32.9
Grand Total:				
Human and Veterinary	$596.4	$698.9	865.1	953.6

* Budgeted.
Source: PMA Annual Survey Report.

Figure 2-2
Percentage of U.S. Company-Funded
Research and Development Conducted Abroad
1970-1987 *



NEW DISCOVERY

Introduction of New Products in the United States. Since 1940, 1,198 new single-chemical entities (NCE's) have been introduced into the U.S. market. The annual number of introductions since 1962 has been only about one-third to one-half of the levels achieved during the 1950s (Table 2-4).

Changes in the regulatory process since the late 1950s have increased the time needed to test new drugs. From seven to ten years elapse between the discovery of a new drug and FDA approval for marketing. This compares with an average of approximately two years prior to the 1962 Amendments to the Food, Drug, and Cosmetic Act.

As the development time for new drugs has increased, so has the cost of R&D per new drug introduced. A large part of industry R&D expenditures, including basic research and the cost of development for projects that must be abandoned for reasons of lack of effectiveness or excessive risks, cannot be allocated to specific products. For this reason, it is difficult to estimate the full R&D costs for a specific product.

TABLE 2-4

NEW SINGLE ENTITY DRUG INTRODUCTIONS TO U.S. MARKETS
1940-1987

Year	Number of Entities	Year	Number of Entities
1940	14	1963	16
1941	17	1964	17
1942	13	1965	25
1943	10	1966	13
1944	13	1967	25
1945	13	1968	12
1946	19	1969	9
1947	26	1970	16
1948	29	1971	14
1949	38	1972	10
1950	32	1973	17
1951	38	1974	18
1952	40	1975	15
1953	53	1976	14
1954	42	1977	16
1955	36	1978	23
1956	48	1979	15
1957	52	1980	13
1958	47	1981	19
1959	65	1982	26
1960	50	1983	22
1961	45	1984	15
1962	24	1985	20
		1986	24
		1987	20
		TOTAL:	1198

Source: PMA Analysis of Paul De Haen data.

Table 2-5 summarizes the results of six studies that examined the costs of discovering and developing new products in the pre-1962 and post-1962 periods, excluding the costs of capital. These studies document the substantial increase in the cost of bringing new drugs to market. The studies show that post-1962 costs averaged about seven times pre-1962 costs.

TABLE 2-5

RESEARCH AND DEVELOPMENT COSTS* PER NCE DRUG
PRE-1962 VS. POST-1962**

(1980 Dollars)

	Pre-1962 ($ Million)	Post-1962 ($ Million)
Schwartzman	$3.7	$48.6
Sarett	3.4	25.9
Mansfield/Schnee	3.1	-
Clymer	-	56.5
Hansen	-	47.6
Baily	16.0	-

* Excluding the cost of capital.
** Studies examined drugs approved from 1963 through 1975.

Source: Hutt, Peter Barton, The Importance of Patent Term Restoration to Pharmaceutical Innovation, Health Affairs, Spring, 1982.

The study by Hansen is of particular interest. He used an accounting approach and studied R&D expenditures for a sample of new drugs from 1963 through 1975. Because R&D expenditures for a new drug are made over a period of years, these expenditures were capitalized in the study. Hansen found an average cost of $54 million (1976 dollars), including the cost of capital.

Hansen also considered the costs for the major phases of the R&D process--preregulatory and regulatory. The regulatory phase begins with the Investigational New Drug (IND) Exemption required to begin tests in human beings. Hansen estimated that pre-IND expenditures are about equal to those incurred during the post-IND phase.

A new study by Steven Wiggins at Texas A&M University, based on new chemical entities approved between 1970 and 1985, estimates that the total cost for an approved new drug is $125 million in 1986 dollars.[1] Like the Hansen study, this new analysis accounts for the opportunity costs of investing funds several years before a drug can be marketed. The increasing cost of developing a new drug is in part attributable to the increasing research focus on chronic conditions. Drugs intended to treat these conditions require more extensive testing.

[1] Wiggins, Steven N., The Cost of Developing a New Drug, PMA, 1987.

NEW DRUG INTRODUCTIONS: U.S. VS. FOREIGN

Table 2-6 lists for each year the number of introductions by country where the headquarters of the company or institution developing the new drugs were located. A total of 1,771 drugs were introduced from 1961 through 1987. U.S. companies were responsible for 421 or 24.0 percent of the total.

Drug introductions by country where each new drug was first marketed are shown in Table 2-7. The results show that only 7.6 percent of the 1,771 new drugs were marketed first in the U.S., 19.0 percent were first introduced in France, 13.9 percent in West Germany, and 13.7 percent in Japan. In 1987, nearly one-third the new drugs introduced were marketed first in Japan.

A similar study[2] conducted by the U.S. Food and Drug Administration examined annual introductions of original molecules in five countries--France, Germany, Italy, the United Kingdom, and the U.S. The study concluded that about 32 percent of all new drugs introduced in the five countries eventually are marketed in the U.S. About 46 percent of the drugs are introduced in the U.K., while France, Italy and Germany each get 60 to 70 percent of the total number of drugs introduced in the five countries.

The FDA study also looked at the "drug lag" in the five countries--i.e., the length of time that elapses between first introduction of a drug and its introduction in another country. For drugs first introduced between 1960 and 1962, approximately 1.7 years elapsed on average before introduction in the U.S. market. The lag time in the U.S. increased to four years for drugs introduced in the late 1960s, but declined in the early 1970s to about 2.2 years--a figure consistent with the experience for France, Germany and the U.K.

NEW DRUGS, 1940-1987

The long-standing leadership of the U.S. in drug innovation is reflected by the fact that about 62 percent of the new chemical entities introduced in the country since 1940 were U.S. discoveries (Table 2-8). In the U.S. over 90 percent of the new drugs were discovered by private industry.

Table 2-9 shows the distribution of introductions by therapeutic class. Since 1940, the therapeutic class that had the largest number of new chemical entities introduced was anti-infectives, with a total of 222 products.

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[2] A Historical Look at Drug Introductions on a Five-Country Market, OPE Study 60, Food and Drug Administration, March, 1982.

TABLE 2-6
NEW DRUG INTRODUCTIONS BY YEAR AND COUNTRY OF ORIGIN
1961-1987

Year of Introduction	U.S.	France	West Germany	Japan	Italy	Switzerland	Eastern Block	Great Britain	Other countries(a)	Annual New Introductions
1961	31(1)	12	11	7	4	12(1)	3	6	9(1)	93
1962	20	21	15	4	7	8	-	4	14	93
1963	22(1)	21	17(1)	12	2	7	2	9	8	99
1964	15	8	14	8	4	6	5	4	6	70
1965	13	14	10	13	6	7	2	4	4	73
1966	22	19	7	8	3	3	8	4	10	84
1967	20(1)	19	8	7	5	8	9	5(1)	7	87
1968	20(2)	17(1)	12(1)	7	7(1)	5(1)	5	4	10	84
1969	18(1)	23	11	5	9	3	9	3(1)	5	85
1970	21(1)	18	7(1)	7	1	6	4	2	6	71
1971	25	16	5	11	7	6	9	2	10	91
1972	14	13	4	9	9	3	8	3	4	67
1973	10	18	14(1)	1	8	9(1)	9	3	6	77
1974	17(1)	13	9(1)	14	4	5	4	4	8	77
1975	15	7	12	8	5	8(1)	11	4	4(1)	73
1976	17(1)	8	9(1)	2	7	2	5	3	8	60
1977	14	6	13	7	11	3	1	6	6	67
1978	12	10	7(1)	7	4	4(1)	2	4	5	54
1979	14	6	7	7	7	-	1	-	3	45
1980	13(1)	2	9(1)	11(1)	9	4(2)	-	-	3(1)	48
1981	(data not available for 1981)									
1982	8	5	1	10	3	4	1	-	7	39
1983	10	3	9	8	1	4	-	2	2	39
1984	7	5	1	11	5	4	-	2	2	37
1985	18	4	4	14	6	1	-	3	3	53
1986	15(3)	3	7	17(2)	2	-	-	3	3(1)	47
1987	10(1)	6	1	18	5	5(1)	-	4	10	58
Total	421	297	224	233	141	127	98	88	163	1,771
	(14)	(1)	(8)	(3)	(1)	(8)		(3)	(4)	

[a] Argentina, Australia, India, Canada, Portugal, Scandinavia, Benelux, Spain, Austria, and Finland.

Note: Figures in parentheses signify substances developed simultaneously in two countries. The figure in parentheses is always included in the preceding number of substances.

Source: E. Reis-Arndt, Medical Marketing & Media (August 1983): 12 (1961-1980 figures); and "World Drug Introductions," Scrip, various issues (1982-1987 figures). No 1981 figures were available.

TABLE 2-7

NUMBER OF NEW DRUGS, BY YEAR AND COUNTRY OF FIRST MARKETING
1961-1987

Year of Introduction	France	West Germany	Japan	Great Britain	Italy	U.S.	Eastern Block	Switzerland	Other Countries(a)	Annual First Introductions
1961	10	12	6	9	4	27	3	8	14	93
1962	24	18	4	6	11	12	-	5	13	93
1963	20	24	12	17	2	7	2	6	9	99
1964	16	14	5	7	1	7	5	4	11	70
1965	16	14	13	4	6	4	2	4	10	73
1966	24	12	8	8	3	6	8	1	14	84
1967	19	12	11	10	7	5	9	5	9	87
1968	19	15	7	11	4	2	5	4	17	84
1969	25	13	7	7	8	3	8	2	13	85
1970	21	6	8	4	5	6	4	4	13	71
1971	15	5	11	8	7	6	9	6	24	91
1972	14	4	9	7	9	4	8	2	10	67
1973	21	6	2	6	6	6	9	4	17	77
1974	14	5	15	11	5	4	3	4	16	77
1975	10	7	8	5	8	3	10	8	14	73
1976	9	5	2	6	6	2	5	2	23	60
1977	4	18	7	7	13	3	1	3	9	67
1978	15	7	7	6	4	3	2	3	7	54
1979	9	7	7	3	7	4	1	1	6	45
1980	1	13	10	6	7	-	-	3	8	48
1981	(Data not available for 1981).									
1982	6	3	9	3	1	4	1	4	8	39
1983	3	8	7	5	3	1	-	5	7	39
1984	5	4	12	1	5	2	-	3	5	37
1985	5	8	14	4	6	3	-	2	11	53
1986	1	6	23	4	2	6	-	1	4	47
1987	6	1	19	5	5	5	-	4	13	58
Totals	332	247	243	170	145	135	95	98	306	1,771

a Argentina, Australia, Austria, Benelux (Holland, Belgium), Brazil, Canada, Iran, Colombia, Hong Kong, Ireland, Luxembourg, Malaysia, Mexico, New Zealand, Philippines, Portugal, Scandinavia (Sweden, Denmark), South Africa, Spain, Zambia, Israel, Pakistan.

Source: Medical Marketing and Media, August, 1983, p.16; "World Drug Introductions", Scrip various issues (1982-1987 figures).

THE FDA PRE-MARKETING DRUG APPROVAL PROCESS

Before a new drug can be marketed in the U.S., extensive testing must be performed and the FDA must approve the products as being "safe and effective" for its intended uses. Tests begin with animals. If a drug is determined to be safe for limited, controlled clinical trials in humans, a sponsor must submit an Investigational New Drug (IND) application to inform the FDA that efficacy and safety studies in man will be initiated within 30 days unless the FDA objects.

Clinical studies of a new drug in humans are usually divided into three phases. Phase I is an initial, cautious trial in a few healthy persons; Phase II deals with more detailed observations in research subjects who have the disease for which the drug is intended to be effective; Phase III consists of more extensive, often longer tests to ascertain whether the drug is effective for the disease state or syndrome it is intended to treat.

If clinical testing proceeds, substantial record keeping is required throughout the testing period. A sponsor then submits a New Drug Application (NDA) containing documentation of safety and effectiveness studies and manufacturing control procedures to be used in preparing the product.

The attrition rate for prospective new chemical entities as a result of clinical testing is very high. Approximately only one in ten drugs for which INDs are issued go through all clinical phases of investigation. Table 2-10 shows the number of INDs and NDAs filed from 1963 through 1986. The annual number of INDs submitted during this period varied between 671 and 2,112. About half of the INDs submitted are abandoned by the sponsor, usually a pharmaceutical company. Discontinuances usually are based on company evaluations of test results and of the potential of the drug being tested.

PATENT ACTIVITY

Patent activity is another measure of the intensity of pharmaceutical research. A new drug may be the subject of several different patents. Patents may be obtained for new chemical entities, for novel manufacturing processes and for new uses of existing compounds. Tables 2-11, 2-12, and 2-13 show the number of patents issued for drugs and medicines during 1963-1986 and the countries in which the companies that received patents were based. The relative share of patents that were issued for "Drugs and Medicines" to companies based in the U.S. was almost two-thirds from 1963-1972, but declined to 48 percent in 1986.[3]

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[3] The U.S. Patent Office credits patents to the country of residence shown by the inventor on the patent applications.

TABLE 2-8
NEW SINGLE CHEMICAL ENTITY DRUGS INTRODUCED TO U.S. MARKET
BY COUNTRY OF ORIGIN
1940 - 1987

Country of Origin	Solely National Origin (A)	Shared Products (B)[a]	Equivalent Number (C)[b]	Accreditation (A+C)	Percentage of Total 1198 New Drugs
United States	732	10	5.0	737.0	61.5%
Switzerland	80	4	2	82.0	6.8
United Kingdom	73	3	1.5	74.5	6.2
West Germany	64	4	2.0	66.0	5.5
France	38	1	0.5	38.5	3.2
Denmark	17	1	0.5	17.5	1.5
Belgium	19			19.0	1.6
Sweden	16	1	0.5	16.5	1.4
Holland	15			15.0	1.3
Japan	20	1	0.5	20.5	1.7
Mexico	9	2	1.0	10.0	0.8
Italy	11	1	0.5	11.5	1.0
Austria	3			3.0	0.3
Canada	4			4.0	0.3
Australia	2			2.0	0.2
Hungary	2			2.0	0.2
Czechoslovakia	1	1	0.5	1.5	0.1
Argentina	1			1.0	0.1
India	1			1.0	0.1
Norway	1			1.0	
Europe (specific nation unknown)	0	1	0.5	0.5	0.0
Source not ascertained	74			74.0	6.2
TOTAL	1183	30	15.0	1198	100.0%

[a] Column B lists the number of drugs for which a country shared the credit with one or more other countries in the origination of a chemical entity.

[b] Equivalent Number (column C) assigns one-half credit for each shared product introduction under column B, i.e., column B divided by two.

Source: PMA Analysis of Paul De Haen data.

TABLE 2-9

NEW SINGLE CHEMICAL ENTITIES INTRODUCED TO U.S. MARKET
BY THERAPEUTIC CLASS
1940-1987

Therapeutic Class	No. in Group	No. in Subgroup	Percentage
Analgesics	36		3.0%
Migraine Therapy		3	
Narcotics		17	
Nonnarcotics		16	
Analeptics	3		0.3
Antagonists and Antidotes	20		1.4
Antagonists		5	
Antidiuretics		2	
Antidotes			
Antineoplastics		11	
Nonspecified		2	
Anesthetics	28		2.4
Inhalants		5	
Injectables		7	
Local and Topical		16	
Anthelmintics	13		1.2
Antiarthritics (nonhormonal)	12		0.8
Anticoagulants	12		1.1
Anticonvulsants	16		1.4
Antihistamines	37		3.2
Anti-infectives	226		18.9
General		1	
Amoebicides		9	
Antibacterials			
General		14	
Urinary		11	
Vaginal		8	
Antibiotics			
Broad and Medium Spectrum		63	
Penicillin and Derivatives		39	
Topical		5	
Unclassified		3	
Antimalarials		8	
Antituberculars		17	
Fungicides--Systemic		8	
Sulfonamides		33	
Antiparasitics		6	
Tropical Diseases--General		1	

TABLE 2-9
(Continued)

NEW SINGLE CHEMICAL ENTITIES INTRODUCED TO U.S. MARKET
BY THERAPEUTIC CLASS
1940-1987

Therapeutic Class	No. in Group	No. in Subgroup	Percentage
Anti-inflammatory Agents (nonhormonal)	15		1.3
Antinauseants	12		1.1
Anti-obesity Preparations	17		1.5
Amphetamines		10	
Other		7	
Antivirals	5		.4
Ataraxics	58		5.0
Bronchodilators	16		1.3
Cancer Chemotherapy	39		3.5
Immunosuppressants	2		0.2
Cardiovascular Preparations	101		8.4
7.9			
Anti-arrhythmics		11	
Cardiotonics		4	
Hypertensives		7	
Hypotensives		37	
Alkaloids		12	
Vasoconstrictors		1	
Vasodilators			
Coronary		8	
Microcirculatory		2	
Peripheral		9	
Xanthine Derivatives		5	
Other Cardiovasculars		5	
Cholesterol Affecting Agents	14		1.2
Lipotropics		3	
Other		10	
Coagulants	5		0.4
Convulsants	1		0.1
Cough and Cold Preparations	24		2.1
Cough Preparations		12	
Nasal Decongestants		12	
Dermatologic Preparations	55		4.6
Antipruritics			
Local		3	
Systemic		2	
Corticoids--Local		19	
Fungicides--Topical		19	
Other		12	
Diabetic Therapy	12		0.9
Hypoglycemics		11	
Hyperglycemics		1	
Diuretics	38		3.4
Benzothiazides		11	
Other		27	

TABLE 2-9
(Continued)

NEW SINGLE CHEMICAL ENTITIES INTRODUCED TO U.S. MARKET
BY THERAPEUTIC CLASS
1940-1987

Therapeutic Class	No. in Group	No. in Subgroup	Percentage
Enzymes	9		0.8
Eye Preparations	18		1.5
Fertility Agents (nonhormonal)	1		0.1
Gastrointestinal Preparations	73		6.3
Antacids		9	
Antidiarrheals		5	
Antispasmodics		37	
Biliary Tract Therapy		3	
Enemas		2	
Enzymes--Digestive		1	
Laxatives		6	
Other G.I. Preparations		10	
Hematinics	15		1.3
Hemostatics	2		0.2
Hormones	91		8.0
ACTH		2	
Corticoids		33	
Anabolics (Hormonal)		9	
Androgens		6	
Estrogens		21	
Progesterones		11	
Other Hormones		9	
Hospital Solutions	6		0.5
Muscle Relaxants	38		3.3
General		16	
Parkinsonism		12	
Surgical		10	
Oxytocics	5		0.4
Parasympathomimetics	7		0.6
Psychostimulants	22		1.9
Sedatives and Hypnotics	23		1.9
Barbiturates		6	
Nonbarbiturates		17	
Thyroid Therapy	9		0.7
Thyroid Preparation		5	
Antithyroid Preparations		4	
Vitamins and Nutrients	16		1.4
Vitamins		10	
Nutrients		6	
Unclassified	46		3.8
TOTAL	1198		100.0%*

*May not add due to rounding.
Source: PMA Analysis of Paul De Haen data.

TABLE 2-10

NEW DRUG FILINGS WITH FOOD AND DRUG ADMINISTRATION
1963-1987

Year	Original INDs Submitted	INDs Discontinued by Sponsor	Original NDAs Submitted	NDAs Approved	New Molecular Entities*
1963	1066	6	192	71	16
1964	875	215	160	70	20
1965	761	306	221	50	13
1966	715	580	216	50	17
1967	671	627	128	74	16
1968	859	564	108	56	11
1969	956	482	60	39	11
1970	1127	N.A.	87	53	11
1971	923	1167	256	68	14
1972	902	452	272	42	10
1973	822	311	149	77	14
1974	802	399	129	95	23
1975	876	472	137	68	15
1976	855	524	127	101	23
1977	925	802	124	63	21
1978	925	588	121	86	22
1979	940	539	182	94	14
1980	1087	626	162	114	12
1981	1184	353	129	96	27
1982	1467	689	202	116	28
1983	1798	N.A.	269	94	14
1984	2112	N.A.	217	142	22
1985	1904	N.A.	148	100	30
1986	1623	N.A.	120	98	20
1987	1346	N.A.	142	69	21

* FDA's definition of new molecular entities differs from the definition of new chemical entities by Paul De Haen, Inc., a key source for PMA's analysis of new drug introductions and the one used in this book. PMA omits diagnostic agents, although the FDA count of new molecular entities includes these agents. In addition, FDA uses application approval dates, whereas De Haen and PMA use year of introduction to the market. Thus, new molecular entities indicated here for a given year may be based on INDs and NDAs submitted a year or more earlier.

N.A.: Not Available.

Source: Unpublished data, Bureau of Drugs, Food and Drug Administration, U.S. Department of Health and Human Services. New Drug Evaluation Project, Briefing Book, FDA, May 1982, September 1983, March 1986, April 1987.

TABLE 2-11
NUMBER OF NEW U.S. PATENTS FOR
DRUGS AND MEDICINES
BY ORIGIN
1963 - 1986

	NUMBER OF PATENTS															
	1963-1972	1973	1974	1975	1976	1977	1978	1979	1980	1981	1982	1983	1984	1985	1986	TOTAL
TOTAL	8865	1278	1524	1841	2284	2407	2378	1826	2454	2575	2223	1996	2475	2489	2504	39119
U.S. ORIGIN	5776	744	835	1051	1201	1221	1239	917	1211	1313	1043	939	1270	1234	1198	21192
FOREIGN ORIGIN	3089	534	689	790	1083	1186	1139	909	1243	1262	1180	1057	1205	1255	1306	17927
U.S. ORIGIN	5776	744	835	1051	1201	1221	1239	917	1211	1313	1043	939	1270	1234	1198	21192
U.S. CORP. OWNED	5152	664	729	931	1105	1103	1125	823	1057	1154	904	802	1102	1097	1035	18783
U.S. GOVT. OWNED	122	26	23	31	25	25	17	18	33	27	26	28	32	27	27	487
U.S. INDIV. OWNED	480	50	79	81	58	85	90	69	111	123	99	98	125	100	118	1766
FOREIGN OWNED	22	4	4	8	13	8	7	7	10	9	14	11	11	10	18	156
FOREIGN ORIGIN	3089	534	689	790	1083	1186	1139	909	1243	1262	1180	1057	1205	1255	1306	17927
U.S. OWNED	517	79	120	116	157	166	164	140	183	145	145	120	107	142	133	2434
FOREIGN OWNED	2572	455	569	674	926	1020	975	769	1060	1117	1035	937	1098	1113	1173	15493
FOREIGN CORP.	2308	387	492	618	870	965	918	720	993	1034	952	878	1015	1040	1095	14285
FOREIGN GOVT.	2	1	2		1	2	4	2	4	2	17	13	18	10	9	87
FOREIGN INDIV.	262	67	75	56	55	53	53	47	63	81	66	46	65	63	69	1121

Source: U.S. Patent and Trademark Office

TABLE 2-12
PERCENTAGE OF U.S. PATENTS FOR
DRUGS AND MEDICINES
BY ORIGIN
1963 - 1986

	NUMBER OF PATENTS															
	1963-1972	1973	1974	1975	1976	1977	1978	1979	1980	1981	1982	1983	1984	1985	1986	TOTAL
TOTAL	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
U.S. ORIGIN	65	58	55	57	53	51	52	50	49	51	47	47	51	50	48	54
FOREIGN ORIGIN	35	42	45	43	47	49	48	50	51	49	53	53	49	50	52	46
U.S. ORIGIN	65	58	55	57	53	51	52	50	49	51	47	47	51	50	48	54
U.S. CORP. OWNED	58	52	48	51	48	46	47	45	43	45	41	40	45	44	41	48
U.S. GOVT. OWNED	1	2	2	2	1	1	1	1	1	1	1	1	1	1	1	1
U.S. INDIV. OWNED	6	4	5	4	3	4	4	4	5	5	4	5	5	4	5	5
FOREIGN OWNED	*	*	*	*	1	*	*	*	*	*	1	1	*	1	1	*
FOREIGN ORIGIN	35	42	45	43	47	49	48	50	51	49	53	53	49	50	52	46
U.S. OWNED	6	6	8	6	7	7	7	8	7	6	7	6	4	6	5	6
FOREIGN OWNED	29	36	37	37	40	42	41	42	43	43	46	47	44	45	47	40
FOREIGN CORP.	26	30	32	34	38	40	39	39	40	40	43	44	41	42	44	37
FOREIGN GOVT.	*	*	*	0	*	*	*	*	*	*	*	1	1	*	*	*
FOREIGN INDIV.	3	6	5	3	2	2	2	3	3	3	3	2	2	3	3	3

* Less than one percent.
Source: U.S. Patent and Trademark Office

TABLE 2-13
NUMBER OF FOREIGN ORIGIN PATENTS FOR
DRUGS AND MEDICINES
BY COUNTRY
1963-1986

	NUMBER OF PATENTS				
COUNTRY OR ORIGIN	1963-1972	1973-1977	1978-1982	1983-1986	TOTAL
West Germany	682	1063	1324	1004	4073
Japan	513	827	1239	1371	3950
United Kingdom	344	548	885	669	2446
France	426	549	615	484	2074
Switzerland	415	443	492	287	1637
Italy	143	174	301	307	925
Canada	101	137	138	113	489
Netherlands	110	62	104	65	341
Mexico	22	21	5	11	59
Sweden	85	117	115	54	371
Belgium	47	49	110	66	272
Hungary	15	35	100	116	266
Denmark	35	30	34	47	146
U.S.S.R.	10	44	37	28	119
Austria	29	31	33	18	111
Other Countries	112	152	201	183	648
TOTAL	3089	4282	5733	4823	17,927

Source: U.S. Patent and Trademark Office

The pharmaceutical industry is the major source in the U.S. for discovering and developing drug products, and patent protection provides necessary incentives to stimulate investment of millions of dollars in research and development. By providing inventors with an exclusive right for 17 years to sell these inventions in the U.S., patents enable companies to realize adequate returns on their substantial investments. New medicines help to improve the health of people in this country and, therefore, great social benefits result from the patent protection given to the inventors of these products. Patents also stimulate additional research by providing useful data for other research efforts.

A patent application is usually filed as soon as a chemical compound shows promising pharmacological activity. Extensive testing is usually required, however, to determine whether a compound can be developed for practical use as a medicine. Such testing in animals and man - and processing through the IND and NDA phases - often continues for years after a patent has been granted. This reduces the patent-protected marketing time during which a company may recover its investment in the product.